MTRE
A Member of Mennen Medical Group

USER MANUAL

CritiCool®

Thermo Regulation System

DDT- 136-000 Rev H

November 2014

For CritiCool machines with 100-OPT99

CE
0473

Conformity according to the Council Directive 93/42/EEC

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Important Notice

Patent Nos. US 6,500,200 B1 , US 5,508,831 B1, US 6,685,731 B1

Disclaimer

MTRE is not responsible for any consequential or incidental damages or expenses of any kind, impairment of or damage to other goods or to any third party resulting from loss of use of the system caused by or due to the following:

a. Installed, operated, maintained contrary to MTRE's instructions, notes or warnings under this manual.

b. Misuse, unauthorized use, negligence, accident, (including fire, water, explosion, smoke, vandalism, etc.).

c. Ignoring any of the warnings, precautions and safety measures indicated in this manual.

d. Replace, repair or alter not by MTRE's authorized personnel.

e. Anyone other than MTRE's authorized and certified personnel removes, casing and/or attempts to make or makes any internal changes, removals, attachments or additions to the CritiCool System or components thereof;

f. The power supplied to the System or any part thereof differs from the rated value, or any external device attached by user creates conditions exceeding the tolerance of the System; or

g. The use of accessories and other parts or equipment made by other manufacturers, whether or not warranted by such manufacturers, which have been attached or connected to the System after installation, unless such accessories and other parts have been supplied and attached or installed by the MTRE.

h. Using the system in a contrary manner than indicated in this manual, or using the system for any purpose other than indicated in the manual.

i. Failure to replace the Wrap in each procedure while operating the system. Note that all Wraps are one-use disposable materials and should not be reused.

j. Force Majeure

In no event shall MTRE be liable for loss of use, loss of profits, or other collateral, special or consequential damages.

Use of Manual

The MTRE CritiCool system described in this manual has been designed to meet international safety and performance standards. Only qualified personnel may operate the system, and these operators must first have a full understanding of the proper operation of the system.

The purpose of this manual is to help qualified personnel understand and operate the system. It is important that you read this manual and familiarize yourself thoroughly with its contents before you attempt to operate the system. If you do not understand any part of this manual, or if anything is unclear or ambiguous in any way, please contact your MTRE representative for further clarification.

The information provided in this manual is not intended to replace regular medical training procedures.

This manual should always accompany the system. All qualified personnel operating the system should know the location of the manual. For additional copies of this manual, please contact your MTRE representative.

Training

MTRE or it's authorized distributor will provide training for the system user according to the intended use of the device or system.

The training may be personal or by training the trainers.

The scope of the training is part of the agreement between MTRE or it's authorized distributor and the end user.

It is the responsible of the hospital management to ensure that only users trained to use the equipment efficiently and safely, operate the equipment.

Operator Profile

Connections and device settings should, typically, be performed by a physician (doctor) expert in thermoregulation, with the help of a nurse.

If the system is used in CCU, a Cardiologist should be involved.

A Neonatologist and pediatric Neurologist should also be involved if the treatment is by Hypothermia in the NICU.

Follow-up during the prolonged Hypothermia procedures of 1 to 4 days, should be performed by nurses trained to supervise thermoregulation, with a physician on call.

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CHAPTER 1: SAFETY PRECAUTIONS

Definitions

WARNING—indicates a condition that may endanger the patient or the system operator
CAUTION—indicates a condition that may damage the equipment
NOTE—indicates ways in which the system's operation can be made more efficient.

Intended Use

The CritiCool system is a thermal regulating system, indicated for monitoring and controlling patient temperature.

Warnings

1. The physician must be notified if the patient's temperature does not respond properly, does not reach the prescribed temperature, or if there is any change in the prescribed temperature range. Failure to inform the physician may result in injury to the patient.
2. The patient should be constantly attended by a physician.
3. The misuse of the temperature regulation equipment can be potentially harmful to the patient.
4. Do not plug wet plugs of the human sensors into the sensor sockets of the CritiCool device.
5. The user should verify that no fluids are present at the skin/Wrap interface during the treatment. Failure to do so can cause lesions on the patient's skin. Following the procedure, a pattern resembling the Wrap may appear for a short period of time on the patient's skin.
6. Pressure sores may appear or develop when soft tissue is compressed between a bony prominence and external surface. The use of the CritiCool system does not prevent this from happening.
   In order to prevent pressure sores, hospital routine care should be taken during long themoregulation procedures.

7. Before initiating maintenance procedures as described in Chapter 6, disconnect the power cord from the power source.
8. Do not lift or move the patient by means of the Wrap. This may cause tearing and water leakage.
9. Use only reusable core sensors or disposable sensor adapters supplied by MTRE.
10. The technical principles, clinical applications, and risks associated with circulatory support must be thoroughly understood before using this product. Read the entire manual before attempting to activate the system. Completion of the training program prior to using the CritiCool system is mandatory.
11. The repair, calibration, and servicing of the CritiCool system should be performed only by MTRE Ltd. or authorized agents trained by MTRE Ltd.
12. Prevent any thermal isolation, such as a pillow or other items, between the CureWrap and the patient's body.

Precautions

1. Follow the warning notes listed in the various sections of this manual.
2. Only trained personnel, familiar with all system operating procedures and certified only by MTRE Ltd.or authorized agents of MTRE Ltd. are allowed to use the CritiCool system. All hospital personnel using the CritiCool system must complete the CritiCool training program.
3. The repair and servicing of the CritiCool device should be performed only by qualified medical equipment service technicians certified by MTRE Ltd. or authorized agents of MTRE Ltd.
4. If moisture or leaks are discovered in the connecting hose and/or Wrap, turn off the CritiCool device, disconnect the power cable from its power source, and correct the problem before proceeding.
5. The desired set-point temperature should be fixed only as prescribed by and under the order of a physician.
6. The default setting is intended to induce hypothermia. The system provides the physician with the option of selecting a body temperature in the range of 30°C to 40°C (86°F-104°F).
7. If the device sounds an alarm and/or presents a display other than the standard MTRE display, the operator should proceed according to the display message and/or the troubleshooting instructions
(see Chapter 7 Troubleshooting).

8. Avoid folds in the Wrap—these may obstruct water flow.
9. Do not block the CritiCool device ventilation grilles. Air must be able to flow freely in and out in order to keep the device cool.
10. Do not use de-ionized or distilled water. Use tap water only.
11. When X-ray imaging is performed on a patient wearing a Wrap, shadows from the Wrap may appear on the X-ray film.
12. Avoid inserting any sharp object between the patient and the Wrap.

EMC Safety

For safe use of the CritiCool it is required to keep the CritiCool at safe distance from devices emitting radio frequency energy.

Refer to Appendix B for recommended separation distances between the CritiCool and RF source.

CAUTION! *Power interrupts affect the functionality of the system, depending on the mode of operation*
- Interrupts longer than 10 seconds return the machine to the Start-up Screen. A beep is heard when the power is returned to indicate that the machine has returned to the StartUp screen.
- Interrupts shorter than 10 seconds return the machine to the mode that was operating before the interruption, but a warning will appear.

IMPORTANT! *Make sure to read the messages in order to ensure correct reactivation of the machine.*

Improper Use

Improper use of the CritiCool system can lead to skin lesions, electrical hazards, and severe changes in body temperature.

WARNING!!! *The technical principles, clinical applications, and risks associated with circulatory support must be thoroughly understood before using this product. Read the entire manual before attempting to activate the system. Completion of the training program prior to using the CritiCool system is mandatory.*

CAUTION! *U.S. Federal law restricts this device to sale by or on the order of a physician.*

Labels

CritiCool Device Labels

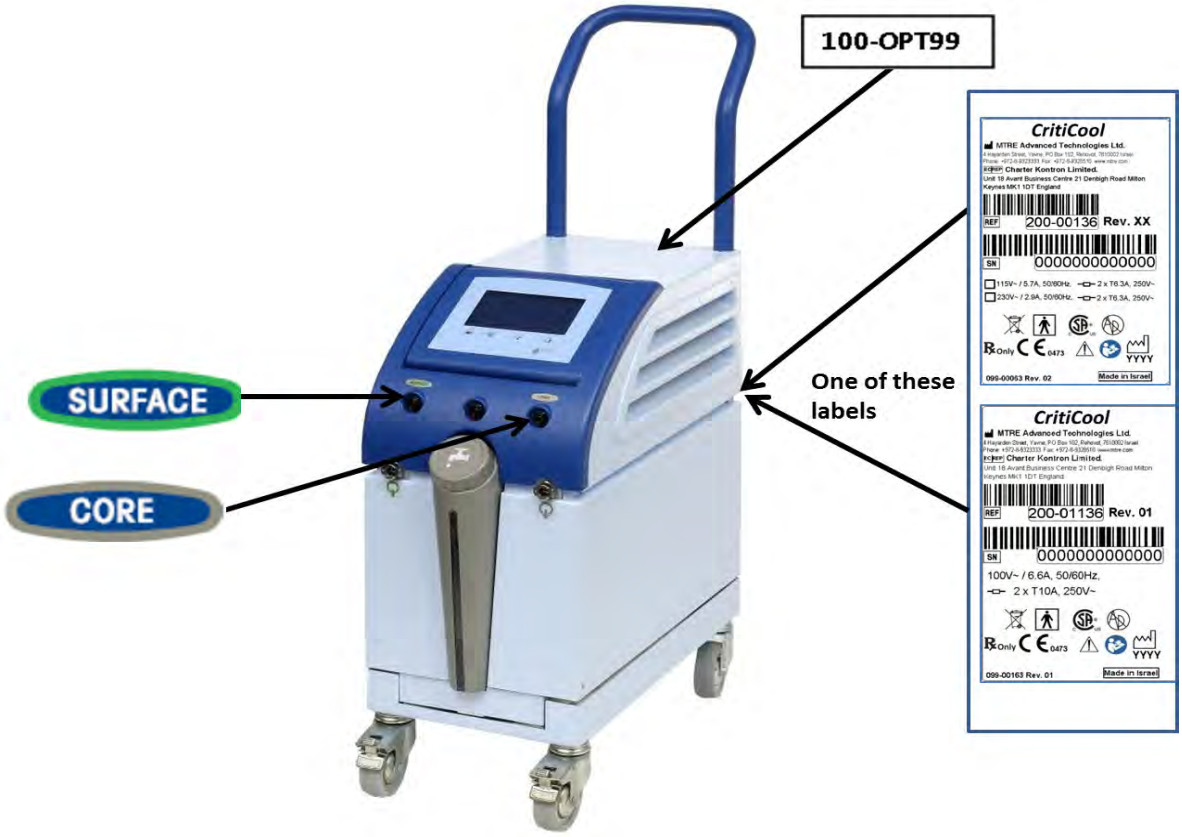


Figure 1-1: Label Placement for the CritiCool Device

Label Symbols

Table 1-1: Key to Label Symbols

Symbol	Description
	Location of core sensor socket
	Location of surface sensor socket
	AC Voltage
	Fuse
	CE mark of conformity indicates that the product has received the European approval for MDD 93/42/EEC.
	Equipment not suitable in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide
	Refer to user manual
	Type BF equipment
	Recycle

Table 1-1: Key to Label Symbols

Symbol	Description
	Date of manufacture
	CSA symbol indicates that the product has received the approval of the Canadian Standards Association.
xx - yyyy	Machine Version - Machine serial number
	Do not push
	Refer to Instruction manual / booklet
	Restricts the sale and use of this instrument to qualified medical personnel only.

CHAPTER 2: SYSTEM DESCRIPTION

General Description

A growing number of cases require a solution for controlling patient temperature in various hospital settings. Inducing hypothermia or simply controlling fever is beneficial and sometimes vital.

The CritiCool system induces, maintains, and reverses hypothermia in an effective and precise manner. The desired temperature is preset by the physician with a possible range of target temperature from Hypothermia to Normothermia.

CritiCool is a member of MTRE's product family of body temperature regulating systems: Allon 2001, CritiCool including ThermoWraps, CureWraps and accessories.

The system is composed of two elements, the CritiCool device, and the CureWrap. The CritiCool device functions as a control unit and a cooling/heating pump, which circulates water. The control unit constantly monitors the Patients' core temperature through specific sensors, and using its on-board body temperature control algorithm, delivers the optimum water temperature to reach the desired set point temperature. The cooling/heating pump brings the water to the required temperature and the pump circulates it through the specially designed CureWrap.

The CureWrap is a flexible 3D single piece design, through which the water circulates. It is designed to be in close contact with a large area of the body, thus allowing optimization of energy transfer. The MTRE garment is proprietary to MTRE and this is the only garment authorized to be used with the Thermoregulation Device.

CritiCool System

The CritiCool system consists of the following elements:

- CritiCool device
- Wrap
- Accessories

CritiCool Device

The CritiCool device has a microprocessor that controls the water temperature flowing into the Wrap worn by the patient. The decision as to the correct water

temperature is based on the desired set point temperature and the actual measured patient temperature (core and surface).

Water pressure in the Wrap is regulated by timed pauses of the flow during clinical operation.

The CritiCool device is equipped with a handle for easy transport.

External Features

Front View

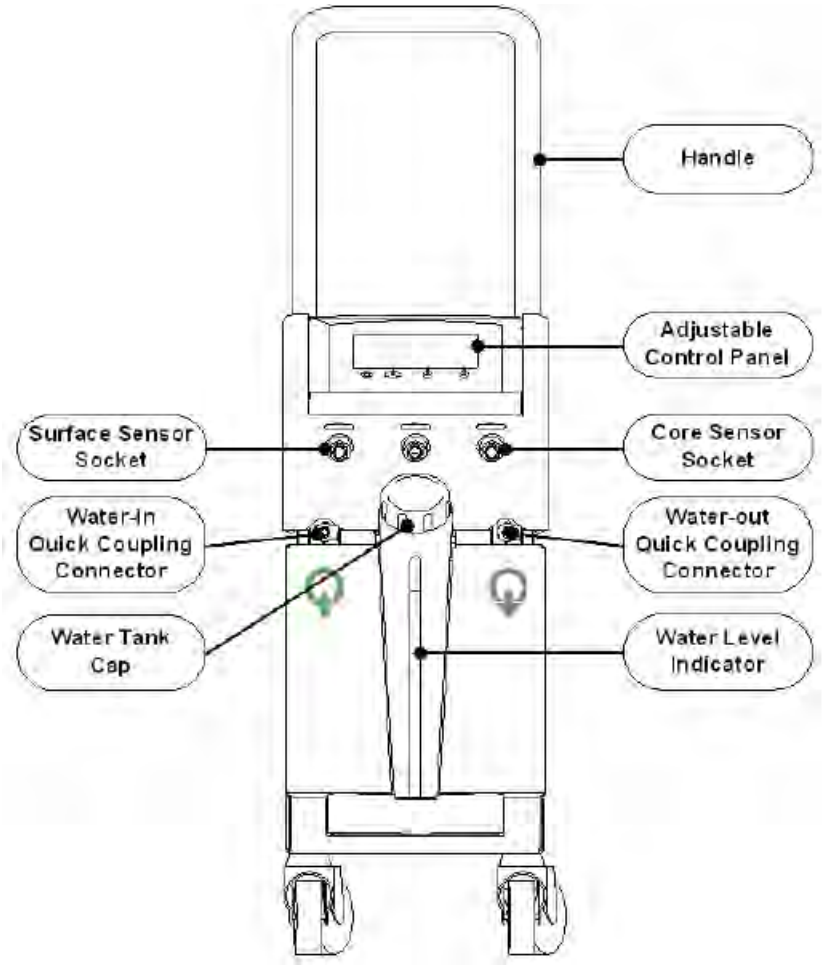


Figure 2-1: Front View

Side View

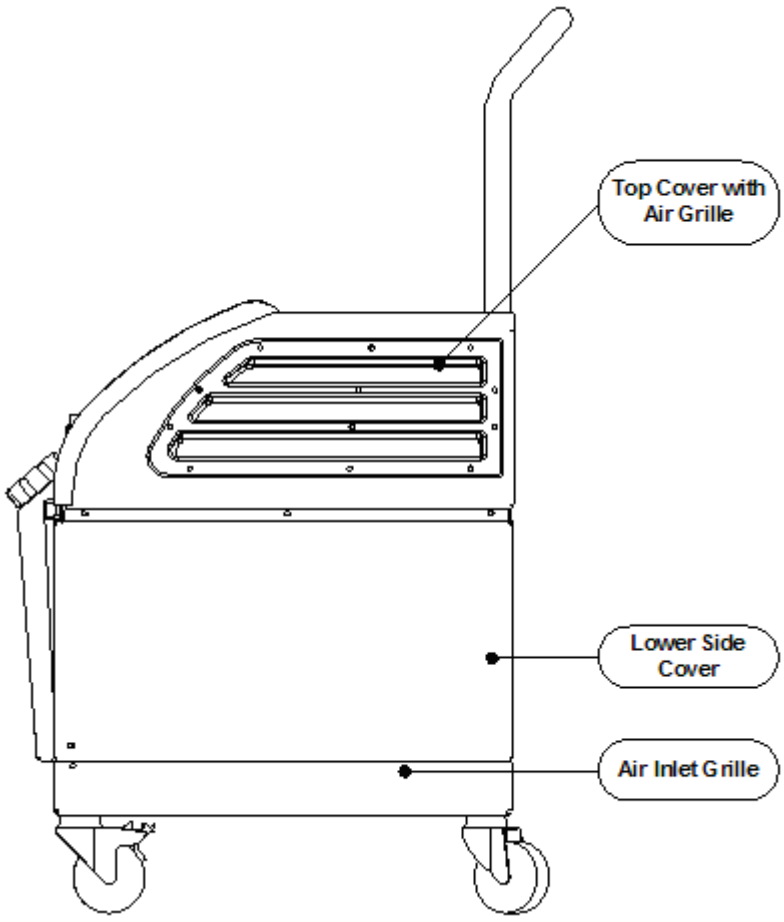


Figure 2-2: Side View

Rear Panel

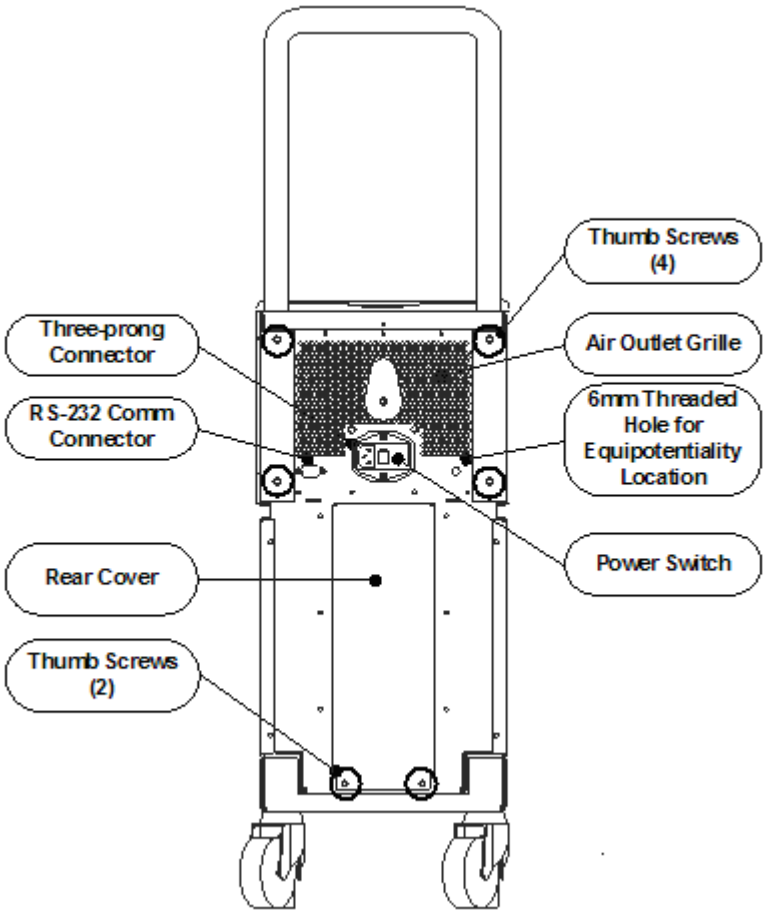


Figure 2-3: Rear View

Wrap

General

The Wrap is a one-piece wrap with a one-inflow and a one or two-return water connection. It is designed to facilitate the wrapping of individual parts of the body (chest, arms, thighs, etc) to maximize surface coverage.

The MTRE garment is proprietary to MTRE and this is the only garment authorized to be used with the Thermoregulation Device.

Description and Intended Use

The Wrap is:

- Disposable
- Biocompatible
- Latex free
- Antistatic
- Inflatable
- Adjustable

Each section of the Wrap is separately wrapped around the appropriate area of the patient (e.g. chest, arms and thighs) to ensure maximum body surface coverage.

The water's exit and entrance points are short sections of tubing integrated with a Quick Coupling Connector (QCC) and welded to convenient locations on the edges of the Wrap.

The Wrap design allows the physician user to cover a maximum surface area as needed.

WARNING!!! *The Wraps are defined for single patient use only. Reusing may cause cross contamination and/or irritation.*
The Wraps' performance was validated only to the defined usage duration (see below).

Selected Wrap Design

MTRE offers disposable Wraps in a wide range of sizes.

CureWrap

- **Material**
  - **Patient side**: Non-Woven PP
  - **Exterior**: Brushed Loop Fabric
- **Usage duration –** Wrap is durable for up to 14 days. However, it is recommended to replace the Wrap at least every 5 days, due to high probability of soiling.
- **Fastening method –** Velcro (unlimited repeated use)
- **Models:**
  - **One Adult size** - One water inlet, two outlets
  - **Pediatric sizes** - One water inlet, one outlet

- **Infant sizes** - One water inlet, one outlet

NOTE:*Select the Wrap according to the patient's size*

NOTE:*Each garment contains a 33mg chlorine tablet (Cl) that prevents contamination of the circulating water and the hydraulic system of the CritiCool.*
The tablet is usually located in the small tube connector of the Wrap.
In some instances of prolonged storage the tablet might move into the Wrap itself, and this may cause brown stains to appear on the Wrap which are noticeable when the Wrap is opened. This staining does not interfere with the operation of the Wrap and the Wrap can be used as normal. The staining usually disappears after exposure to UV or sunlight.

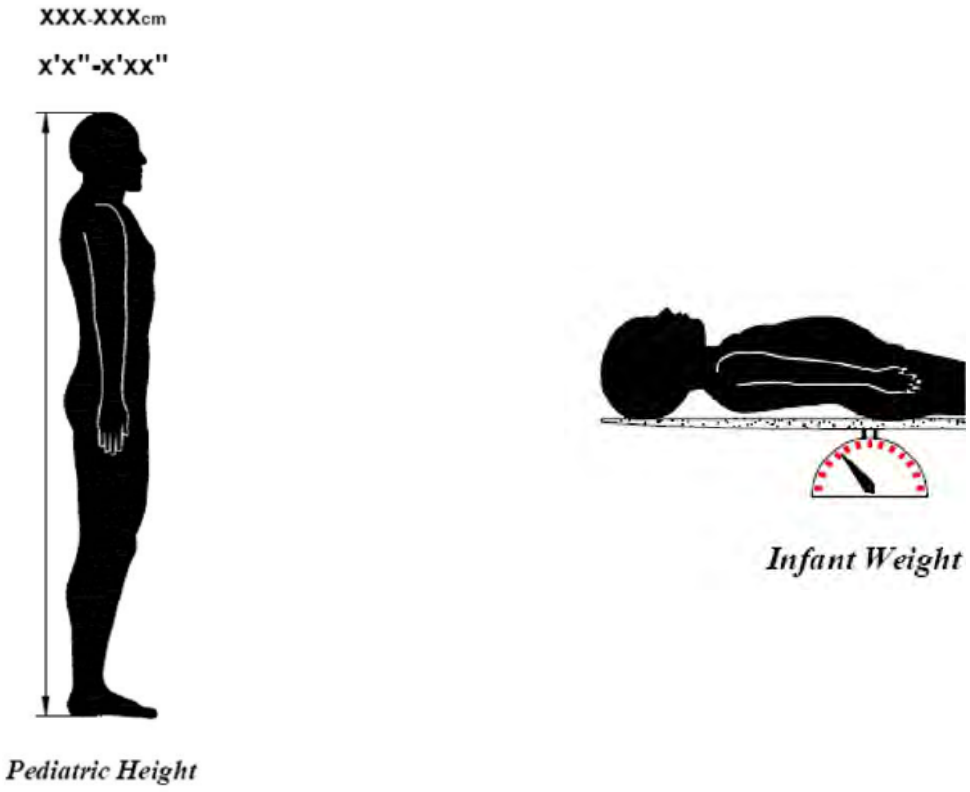


Figure 2-4: Measurements

Table 2-1: Cure Wrap

TW/CW	*Type*	*P/N*	*Number of wraps / Box*	*Patient Size/ Weight*	*Wrap Height/ Width (m)*
Cure Wrap	**Adult**	**508-03500**	**Box (X8)**	**168-180cm (over 66")**	**2.030 / 1.354**
	Infant	**508-03518**	**Box (X8)**	**Up to 4Kg**	**0.659 / 0.448**
		508-03521	**Box (X8)**	**4-7Kg**	**0.698 / 0.602**
Pediatric Cure Wrap	**Small**	**PED-SM008**	**Box (x8; multi size)**	**Up to 4Kg (X4), 4-7Kg (X4)**	**0.659 / 0.448 0.698 / 0.602**
	Medium	**PED-MD008**	**Box (x8; multi size)**	**7-11 Kg (X4), 79-91cm (X4)**	**0.981 / 0.628 1.118 / 0.740**
	Large	**PED-LA008**	**Box (x8; multi size)**	**91-104cm (X4), 104-122 cm (X4)**	**1.225 / 0.841 1.390 / 1.054**
	X-Large	**PED-XL008**	**Box (x8; multi size)**	**122-135cm (X4), Over 135cm (X4)**	**1.582 / 1.1193 2.030 / 1.354**

Accessories

The following accessories are needed in order to operate the CritiCool system the :

1. **Human Temperature Sensors**

   Intended Use

   Core temperature sensors are used to measure the patient's core temperature and for thermoregulation of the patient's body.

   Surface temperature sensors are used to measure the patient's surface temperature, in a location not covered by the CureWrap and for thermoregulation of the patient's body.

1.1. Reusable Sensors

There are three color-coded sensors: Core (gray), Surface (green), and Infant Core (gray). Both core and surface sensors must be plugged into the CritiCool device. The core sensor must be inserted and the surface sensor must be attached to the patient for the device to function properly.

1.2. Disposable Sensors

Disposable sensors are attached to two color-coded adapters: gray (Core) and green (Surface). The core sensor must be inserted and the surface sensor must be attached to the patient for the device to function properly.

Sensors and adapters are guaranteed for one year.

WARNING!!! *Use reusable core sensors or disposable sensor adapters supplied by MTRE.*

Sensors can be either Reusable or Disposable according to Staff custom.

1.3. Reusable Sensors:

1.3.1 Reusable Core Sensor (Part No. 014-00020):
The 10F core sensor (gray) measures core body temperature when inserted into the patient’s body. The plug of the sensor cable is plugged into the gray core sensor socket at the front of the CritiCool device. The other end is inserted into the patient and measures core body temperature.

1.3.2 Reusable Infant Core Sensor (Part No. 014-00005):
The12F infant core sensor (gray) measures infant core body temperature when inserted into the patient’s body. The plug of the sensor cable is plugged into the gray core sensor socket at the front of the CritiCool device. The other end is inserted into the patient and measures core body temperature.

1.3.3 Reusable Surface Sensor (Part No. 014-00021):
The surface sensor (green) measures body surface temperature when attached to the patient's skin. The plug of the sensor cable is plugged into the green

surface sensor socket at the front of the CritiCool device. The other end is attached with adhesives to the patient's skin.

1.4. Disposable Sensors:

1.4.1Disposable Surface Sensor (Part Number 014-00321):

The disposable surface sensor is attached to the surface sensor adapter (green) (Part No. 014-00129). The plug of the adapter is plugged into the green socket (marked surface at the front of the CritiCool device. The sensor is attached with adhesives to the patient's skin and measures surface body temperature.

1.4.2 Disposable Core Sensor (Part Number 014-00322)

The disposable Core sensor is attached to the core sensor adapter (gray) (Part No. 014-00028). The plug of the adapter is plugged into the gray sensor socket (marked core) at the front of the CritiCool Device. The sensor is inserted into the patient (esophagus/rectum/bladder) and measures core body temperature.

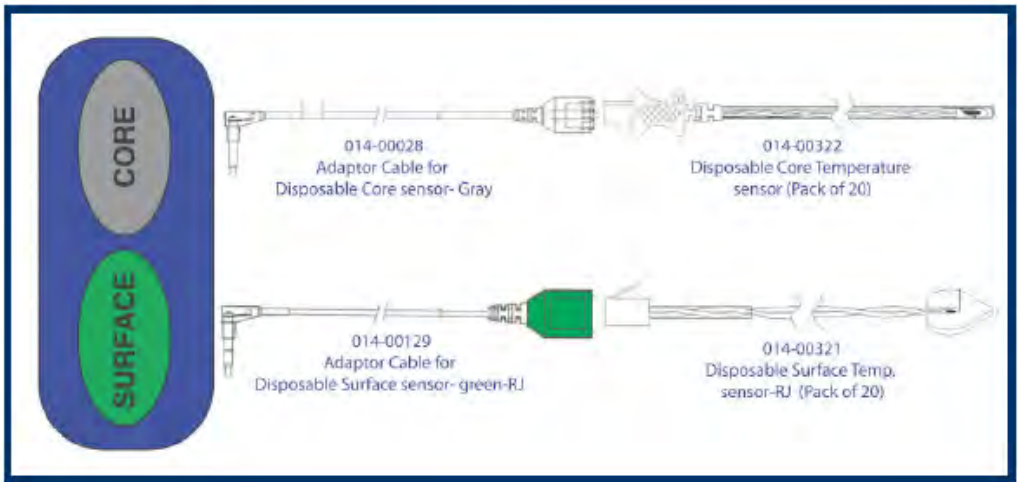


Figure 2-5: Disposable Sensor connection

Table 2-2: Disposable Sensors

Part number	*Description*
Surface	
014-00129	**Adaptor Cable for Disposable Surface sensor- green-RJ**
014-00321	**Disposable Surface Temperature sensor-RJ (Pack of 20)**
Core	
014-00028	**Adaptor Cable for Disposable Core sensor- Gray**
014-00322	**Disposable Core Temperature sensor (Pack of 20)**

Table 2-3: Sensor and Data Provider Input Specifications

Part No.	Name	Description	Accuracy	Resolution	Type
014-00020	**Core**	Inner body temp.	± 0.3°C	± 0.1°C	Medical Grade Thermistor
014-00021	**Surface**	Skin temp.	± 0.3°C	± 0.1°C	Medical Grade Thermistor
014-00005	**Core Infant**	Infant Inner body temp.	± 0.3°C	± 0.1°C	Medical Grade Thermistor

2. **Detachable Electric Power Cable & Plug**
   See Table 5-2, “Accessory Part Numbers,” on page 5-2.
3. **Connecting Tubes for CureWrap**
   Two flexible 2.5 m long, color-coded connecting tubes, connect the CureWrap with the CritiCool device to enable the flow of water between them.

   3.1 Connecting Tubes for Adult CureWrap (Part No. 200-00147)

   The tubes are supplied as a paired unit with two male Quick Coupling Connectors at the CritiCool device end and with three female Quick Coupling Connectors at the CureWrap end.

   3.2 Connecting Tubes (Part No. 200-00109)

   The tubes are supplied as a paired unit with two male Quick Coupling Connectors at the CritiCool device end and with two female Quick Coupling Connectors at the Wrap end.
4. **Male Connector for Draining Water Tank (Part No. 002-00069)**
5. **Spare Water Filter (Part No. 200-00130)**
   For annual filter replacement - packed in the accessory box
6. **Handle (Part No. 007-00365)**

System Specifications

See the following page for system specifications.

CritiCool Specification

The **CritiCool**, one of **MTRE**'s Temperature Regulating systems, induces, maintains, and reverses hypothermia in an effective and precise manner. The desired temperature is preset by the physician with a possible range of target temperatures from Hypothermia to Normothermia. The system is composed of two elements, the **CritiCool** device, and the CureWrap. The **CritiCool** device functions as a control unit constantly monitoring the Patient's core temperature and as a cooling/heating pump which brings the circulating water to the required temperature by using its on-board body temperature control algorithm. The **CureWrap** is a flexible single piece garment, through which the water circulates. It is designed to wrap the patient and be in close contact with a large body area, thus allowing optimization of energy transfer.

HARDWARE

Heat Exchangers
- Peltier Technology (TECs)

Water tank
- Tap water usage
- Tank Capacity: 6 liters (1.6 gal.)

Water Temperature
- Water Temperature Accuracy ± 0.3ºC (0.4ºF)
- Water Temperature (outflow) 13-40.8ºC (55-105.4ºF)

Pump
- Water Circulating Pump
- Pump Rate: 1.2 L/min
- Protected by 263 micron filter

Patient Temperature Channels
- 2 Channels: Core, Surface
- YSI400 Series Probes
- Body Temperature Range:15^{0}C to 44^{0}C (59^{0}F to 111.2^{0}F)
- Body Temperature Accuracy ± 0.3ºC (0.4ºF)

Temperature and Pressure Sensors
- System Sensors:
  - ◊ 3 Internal Temperature Sensors: Water in, Water out, Thermostat
  - ◊ 2 Pressure Sensors
- Safety measures:
  - ◊ Over pressure protection and alarm
  - ◊ High water temperature protection and alarm

Physical Dimensions
- Mobile Unit with 4 wheels and 2 brakes
- 260 mm W x 625 mm D x 940 mm H / (10.23"W x 24.6"D x 37"H)

Net Weight
- 34 kg / 75 lb

Electricity Input Power (2 Options)
- 230/115 VAC (switchable) with isolation transformer 50/60 Hz
- 100 VAC with isolation transformer 50/60 Hz

Maximum Current
- 230VAC 2.5A-3A/ 115VAC 4.8A-5.0A
- 100VAC 6A-6.6A

Environmental Operating Conditions
- Temperature: +5°C to +40°C (41°F to 104°F)
- Humidity: 10% to 93%, non-condensing
- Should not be used in an atmosphere with flammable anesthetic mixtures.

Environmental Storage Conditions
- Ambient temperature range of -15°C to +68°C (–40°F to 158°F)
- Humidity: 10% to 93%, non-condensing
- Atmospheric pressure range of 500 hPa to 1060 hPa
- Maximum storage time without servicing is 52 weeks

External Ports
- 1X Isolated Serial Port

LCD Display
- Size: 5.5"
- Resolution: 240x128 pixels

SOFTWARE

Displayed Information
- Mode of operation
- Set point temperature (Range: 30^{0}C - 40^{0}C)
- Core Temperature
- Surface temperature
- System status and alarms
- Technician mode display

Operating Modes (Neonate or Adult Configurable)
- Mild Hypothermia (Cooling)
- Controlled Re-Warming (Automatic)
- Normothermia
- Stand-By
- Emptying

Languages
- German
- English
- French
- Finish
- Turkish
- Italian
- Dutch
- Spanish
- Portuguese
- Swedish
- Norwegian
- Danish

User Interface
- 4 soft push buttons

ACCESSORIES

Temperature Sensors
YSI 400 Series Probes
- Reusable Core - Adult/Infant (Autoclavable/Non-Autoclavable)
- Reusable Surface
- Disposable core (one size)
- Disposable core adapter
- Disposable surface (one size)
- Disposable surface adapter

CureWraps
- Sizes range:
  - ◊ Length 65cm-203cm (25'- 80')
  - ◊ Width 44cm-135 cm (17'- 53')
- Wrap is durable for up to 14 days
  It is Recommended to Replace Wraps at least every 5 days
- Each garment contains a 33mg chlorine tablet
- Wrap Storage Span: 5 years
- Storage Conditions:
  - ◊ Humidity: 10%-90%
  - ◊ Temperature: 10°C to 27°C (50°F to 80.6°F)
- Transport Conditions:
  - ◊ Humidity: 20% to 95%, non-condensing
  - ◊ Temperature: -20°C to 60°C (-4°F to 140°F)

External Water Tubes
- Adult—Dual/Triple connector to garment
- Pediatric/Infant—Dual connector to garment

CliniLogger
Detailed information on next page

REGULATORY
- CE 0473—Class IIb
- Health Canada - 64184
- FDA Clearance - K083662—Class II
- IEC 60601-1 3rd Ed.
- IEC 60601-1-2 3rd Ed.
- EMC per IEC 80601-2-35 : 2009
- Type BF
- IP X0

CritiCool Specification
CliniLogger

CliniLogger is an external device to CritiCool™\Allon2001 Thermoregulation systems, that is used to collect the system data during the thermoregulation procedure.

Connector

- DB9 female connector for serial interfacing to Criti-Cool™\Allon2001

Size

systems or general PC

Controller

- 35x65 mm
- MSP4301611 Micro controller with the following features:
  - ◊ Built in Flash & RAM
  - ◊ Built in UART & SPI

Memory

- ◊ Built in DMA controller

Power requirement

- Flash memory capacity :2MB (17days—FIFO)
- 5 Volt DC supplied from the CritiCool™\Allon2001 systems or PC
  - ◊ < 20 mA
  - ◊ < 100 mW

LED

- BiColor (Green / Red)

Data Storage Rate

- 1 minute interval recordings

Serial communication

- RS232:
  - ◊ 19200 bps to CritiCool™\Allon2001 systems
  - ◊ 115200 bps to PC

Data Collected

- Temperatures: Setpoint, Core, Surface
- Water Circulation On/Off
- Water Heat/Cool

CHAPTER 3: INSTALLATION

Pre-installation Requirements

Space and Environmental Requirements

The CritiCool™ device is supplied on a trolley as a mobile unit for user convenience. It must be located no less than 5 cm (2") from other objects to avoid the impairing of ventilation to the CritiCool device.

The following dimensions should be considered when placing the CritiCool device:

260 mm W x 625 mm D x 940 mm H / (10.23"W x 24.6"D x 37"H)

Electrical Requirements

230/115VAC 500W or 100 VAC

CAUTION! *Verify that the voltage switch is set for the local voltage.*

Unpacking and Inspection

The CritiCool device has undergone full quality assurance testing before shipment and should be operational upon delivery.

The unit should be unpacked, installed and tested only by MTRE's authorized personnel. No attempt should be made by the purchaser to unpack or assemble the unit alone.

NOTE: *Report any container damage prior to opening the container, or any unit damage prior to unpacking, installation, or testing to your MTRE distributor.*

Assembling the Handle

➤ ***To assemble the handle:***

1. Release the four thumb screws by hand.
2. Slide the two ends of the handle into the holes in the top cover (pay attention to the direction of the curve in the handle) until the handle is inserted all the way in (see Handle Assembly3-1).
3. Press in and screw the four thumb screws by hand (do not use force when screwing) to secure the handle and the top cover.

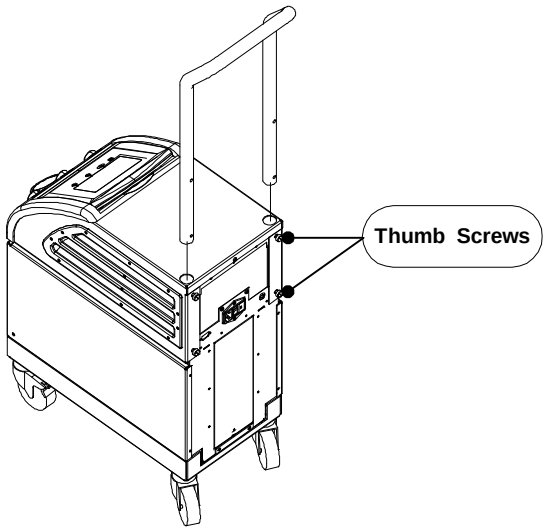


Figure 3-1: Handle Assembly

Equipment List

The CritiCool system includes the following:

- CritiCool device
- Handle
- Power cord
- User manual
- Quick reference guide
- Accessories Kit for CritiCool - one of the following: (See Table 5-2)
  - 200-00300
  - 200-00310
  - 200-00320
  - 200-00330

Moving the Unit

Preparation:

Before moving the unit:

1. Ensure that the CritiCool device is off by pressing the ON / OFF switch.
2. Ensure that all electrical connections are disconnected.

Locking and Unlocking the Trolley Wheels

The CritiCool device trolley has four wheels. The front wheels are fitted with a brake. The brake lever is located over the wheel. To lock the wheels, firmly press the lever. To release the wheels, lift the lever.

When the unit is stationary, the brakes must be in the locked position. Release the brakes only when transporting the unit.

Storage Conditions and Transport

Storage

CritiCool Device

CAUTION! *Use protective means to avoid excessive vibration during device transport.*

Store the CritiCool device in a clean and dry area with:

- An ambient temperature of -15°C to +68°C (-40°F to +104°F)
- A relative humidity range of 10% to 93%
- An atmospheric pressure range of 500 hPa to 1060 hPa.

CureWrap

Storage: Store the CureWrap packages in a clean and dry area with the following conditions:

- **Humidity**: 10%-90%
- **Temperatur**e: 10°C to 27°C (50°F to 80.6°F)

Transportation: The CureWraps can be transported in the following Transport Conditions:

- **Humidity**: 20% to 95%, non-condensing
- **Temperature**: -20°C to 60°C (-4°F to 140°F)

CHAPTER 4: OPERATING INSTRUCTIONS

General

This chapter contains:

- Application Specification
- A description of the controls, indicators and connections for the CritiCool device.
- Detailed operating instructions for the CritiCool system for the different modes of operation.

Application Specification

Indication for Use

The CritiCool indication for use statement is:

The CritiCool is intended to maintain pre-set body temperature as determined by the physician. It can also be utilized to maintain normal body temperature during surgical procedures. It is indicated for use in hospital intensive and coronary care units, in operating, recovery and emergency rooms, in burn units, and on medical / surgical floors. This system can be used with adult and pediatric patients.

Location

Patients undergoing thermoregulation procedures will be hospitalize in an ICU (Intensive Care Unit) and will be monitored for their vital signs.

Patient Age and Weight

A set of CureWrap garment is provided to fit any body size and weight. The CritiCool thermoregulation, warning massages and alarm system is same for all ages and body size.

The default setting are different for adults and for neonates. Both can be set by the user per the protocol used at each hospital.

Procedures

The CritiCool is designed for clinical applications such as Mild Hypothermia and Normothermia.

Mild Hypothermia

Mild Hypothermia, is used for treatment of patients that have suffered from hypoxia/anoxia that may have effected the brain.

There are widely accepted protocols for treatment of newborns that have suffered hypoxia during birth [1] and for patients that have survived out of hospital resuscitation due to cardiac arrest [1] .

The treatment is composed of three phases: Fast Cooling, Continuous Mild Hypothermia, and gradual Rewarming.

The duration of the fast cooling phase depends on the patient's size and weight. It will be short for small babies and longer for adult. It may also be affected by patient conditions such as fever and by environment temperature.

The duration of the Mild Hypothermia phase depends on the treatment protocol and will typically be 72 hours in the newborn protocol [1] and 24 to 48 hours in the adult cardiac protocol [1] .

The **Mild Hypothermia** treatment is called in this user manual "Cooling". The fast cooling phase and the continuous mild hypothermia are both achieved by setting the set point to the required hypothermia temperature without modifying the set point until the end of the hypothermia phase.

The **Rewarming** stage will typically take 6 to 8 hours according to the hospital treatment protocol [1] and can be performed manually or automatically using the Rewarming mode of the CritiCool.

Normothermia

In this mode of CritiCool the thermoregulation brings the patient to the Normothermia temperature as fast as possible and stabilizes patient temperature to the set point (Default temperature is 36.5 OC). This mode is typically used in patients with Accidential Hypothermia, in which quick rewarming is the goal of treatment.

1..
a. Circulation.2010; 122: S250-S275 2010 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations.
b.. Resuscitation. 2010 Oct;81(10):1219-76 European Resuscitation Council Guidelines for Resuscitation 2010.
c.. Circulation November 2, 2010, Volume 122, Issue 18 suppl 3 S640-S656 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science.

Controls, Indicators and Connections

This section includes a short description of the following:

- Main power switch
- QCC—Quick Coupling Connectors
- Sensor sockets

The following functions of the CritiCool device are described:

- Cooling
- Warming
- Rewarming
- Empty

Main Power Switch

The main power switch, located at the rear of the unit, switches the CritiCool device ON and OFF.

QCC—Quick Coupling Connector

The Quick Coupling Connectors are located at the front of the CritiCool device, and are connected to the Wrap by the connecting tubes.

➤ ***To connect the connecting tubes:***

1. Before connecting the tubes, press the metal flange on each QCC to ensure 'open position' of the connector.
2. Lock the connecting tubes by pressing them against the connectors; when locked, a clicking sound is produced.
3. Verify that the tubes have been locked by lightly tugging them towards you.

➤ ***To disconnect the connecting tubes:***

1. Press the metal flange and pull out the connecting tubes.

Sensor Sockets

There are two sensor sockets located at the front of the CritiCool device.

➤ ***To connect the Sensors:***

1. Insert the appropriate reusable sensor or disposable sensor adapter into the designated socket.

➤ ***To disconnect the Sensor***

1. Pull the appropriate reusable sensor or disposable adapter out of its socket.

Getting Started

Preparing the System for Operation

➤ ***To prepare the system for operation:***

1. Place the unit in the desired position according to “Space and Environmental Requirements” on page 3-1.
2. Press the brake pedals and lock the wheels to secure the CritiCool device.
3. Remove the water tank feeder cover and pour in cold tap water until the maximum allowable level is reached - (minimum water temperature 13ºC / 55.4ºF)
4. Observe the water-level indicator to prevent overfilling the water tank. Close the water tank feeder cover.

NOTE: *In case of overfilling, see Table 7-1.*

5. Connect the CritiCool device to the power source.

Turning on the System

➤ ***To turn on the system:***

NOTE: *Make sure that tubes and sensors are disconnected.*

1. Turn the main switch, on the CritiCool system, located at the rear of the unit, upwards to the ON position.

At the end of Self Test the alarm is automatically activated.

Cooling Therapy Control Panel

After the self test, the MODE SELECT screen appears with COOLING mode highlighted.

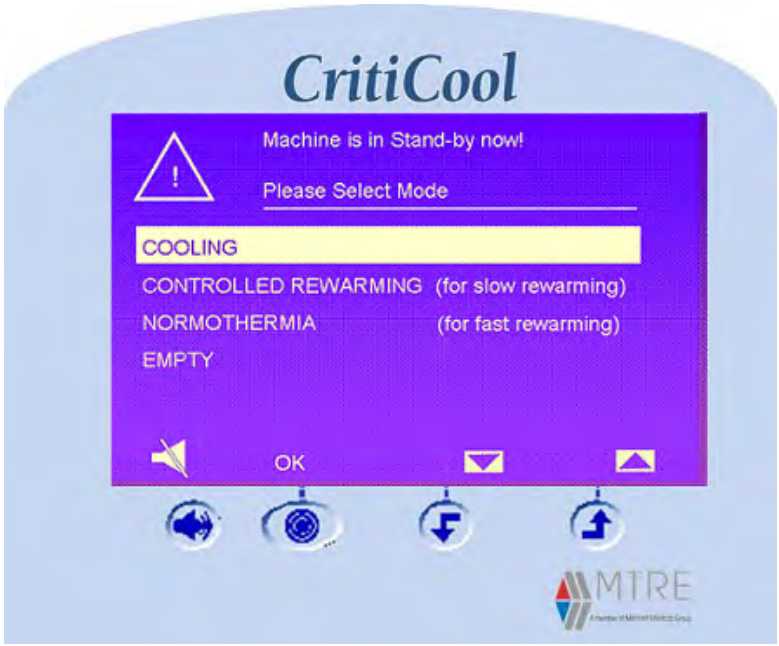


Figure 4-1: Select Mode

Use the Up/ Down arrows to choose the required Mode, and press **OK**.

After a successful registration, the Thermoregulation Control Panel appears (see Figure 4-2).

The adjustable control panel is located at the top of the CritiCool device.

Once the CritiCool device is turned on, all operating functions are controlled through the control panel. The control panel's soft- touch keys and visual displays guide you through each operational phase.

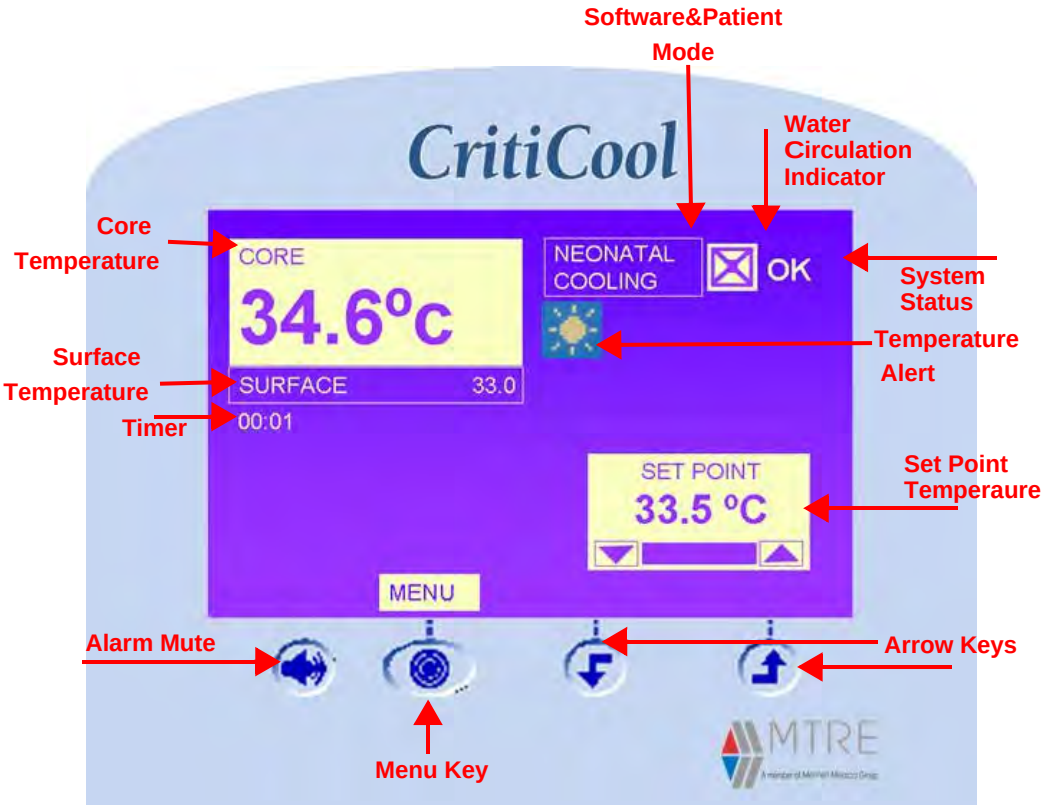


Figure 4-2: Thermoregulation Control Panel

➤ ***To pre-configure the patient mode:***

1. Select **Menu**, this opens a list of options:
   - Standby
   - Mode Select
   - Temp Graph
   - Settings
   - Back
   - Technician
2. Use the up/down arrows to reach **Settings**, press **OK**; the following screen appears.

3. Use arrows to select patient type: **Neonatal** or **Adult**.
4. In this screen you can also choose Language and Temperature Units, and choose the Default Set Point Temperature for Adult patients, and the Default Delta Temperature Step for the Automatic Rewarming mode
5. Click **EXIT** to return to the main screen

The Control Panel

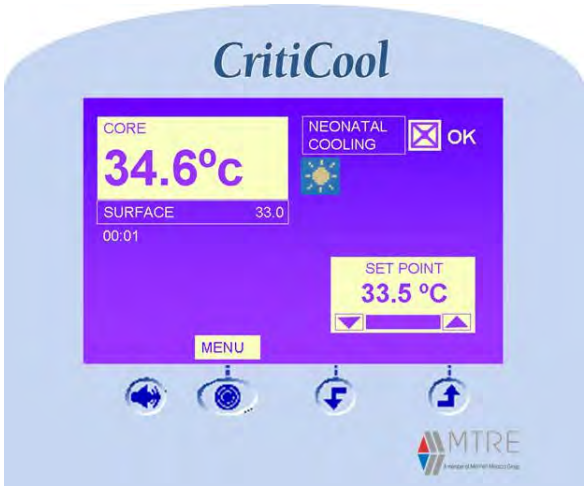


Figure 4-3: Neonatal Cooling control panel

The Control panel displays the following:

- Patient Core and Surface temperatures
- Set Point temperature
- CritiCool Mode and Patient Type,
- **OK** indicator to indicate that the system is functioning correctly
- Moving Flow  icon that indicates that water is flowing through the Wrap.
- Temperature Alert indicator appears if the patient temperature and water temperature in the wrap are not close enough to each other:
  -  is displayed when the water temperature flowing to the wrap is at least 0.5º*C* LOWER than the patient's average temperature
  -  is displayed when the water temperature flowing to the wrap is at least 1.5º*C* HIGHER than the average patient temperature
- Alarm and warning messages that are displayed at the lower part of the panel (see “Operation Panel Messages” on page 4-24).

NOTE: *When you turn the CritiCool on in Cooling mode or when you switch to Cooling mode the default Set Point will be:*
For Adult Cooling : 33.0ºC (this can be changed in the Settings screen)
For Neonatal Cooling: 33.5ºC

Set-Point Set Up

The Set-Point is the temperature to which the thermoregulation system cools or warms the patient's body.

In Neonate mode, the set-point default for cooling is 33.5ºC (92.3ºF).

In the Adult mode, there is an option to configure the default Set Point temperature in the Settings screen (range is between 33 ºC to 36 ºC in steps of 1ºC). The default Set Point temperature that is configured will be the Set Point temprature for the machine upon Start up.

After Start up, it is possible to change the Set Point.

➤ ***To change the set point temperature***

1. Use the up/down arrows to change the **Set Point Setting** panel.

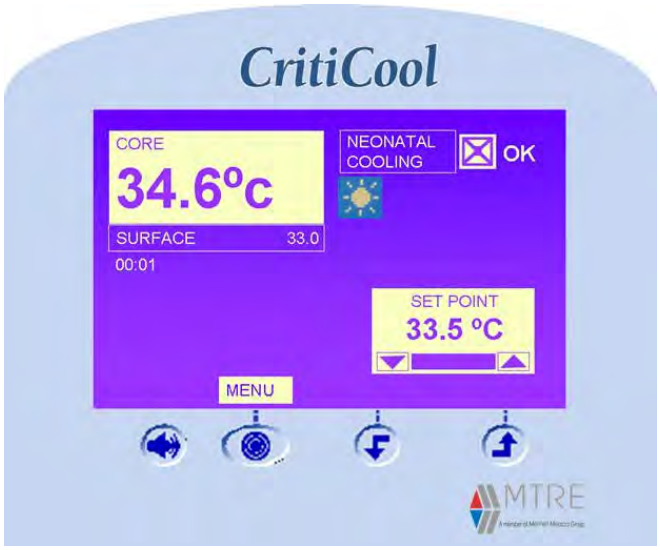


Figure 4-4: Set-Point Setting Panel

Selecting Modes

The MODE SELECT panel enables selection between the modes:

- **COOLING**

  Cooling is the first choice in the SELECT MODE (always highlighted), and is the default mode for most therapies.

  Use this mode for induced mild hypothermia therapies. You should also use this mode for any procedure where you would like Thermoregulation to bring your patient's temperature to a stable Set Point temperature (for example- high fevered patients, patients that it is critical to keep at a stable temperature etc.).

- **NORMOTHERMIA**

  Use this mode for warming, following accidental hypothermia, or for any other instance in which your patient needs to be rewarmed quickly from a very low temperature. You should not use this mode for cooling patients.

  When switching to Normothermia Management, the system will keep the last set point of the preceding mode.

- **CONTROLLED REWARM**

  Rewarming after therapeutic hypothermia is a gradual procedure. This mode provides controlled gradual warming. Each step of the procedure increases the set point temperature by a fixed, small step for a predefined period. The step is always related to the Core temperature reached at the end of the previous stage. You need to set only the final, Target, temperature.

- **EMPTY**

  Use this mode to empty the system from water, prior of storage of the CritiCool.

➤ ***To select a mode:***

1. Press the MENU key.
2. Select the MODE SELECT option to display the MODE SELECT panel.
3. Use up/down arrows to select the required mode.

The selected mode is highlighted.

4. Click **OK t**o activate the mode.

NOTE: *The selected mode is shown on the top of the control panel (see “To pre-configure the patient mode:” on page 4-6).*

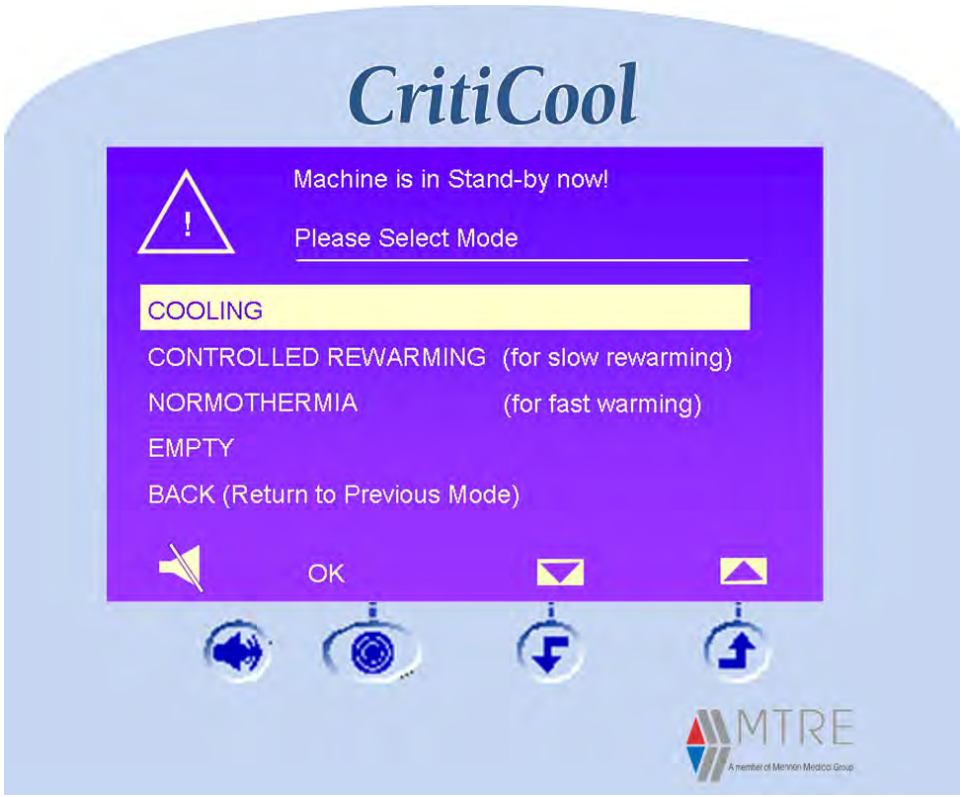


Figure 4-5: Mode Selecting panel

CAUTION! ***Power interrupt***

Power interruption affects the functionality of the system, depending on the mode of operation:

– ***Interruption for less than 10 seconds:***

*1.**During Cooling and Normothermia modes:** The system sounds a 5 second alarm sound, and thermoregulation continues with no change.*

*2. **During Rewarming:** Thermoregulation stops, the system sounds a continuous alarm and a confirmation panel appears. The system cools the water in the tank and sounds the alarm until **Operate** is pressed in the panel for confirmation. It is not possible to mute the alarm sound.*

– ***Power interrupt for longer than 10 seconds:***

Requires turning on the thermoregulation system (see "Turning on the System" on page 4-4)

Controlled Rewarming Setup

The Controlled Rewarming mode enables warming the patient gradually according to a fixed setup.

You can choose the required step rate in the Settings screen. Available rates are- 0.1°C, 0.2° C, 0.3° C, 0.4° C, 0.5° C per hour.

➤ ***To choose the rate:***

1. Press **Settings** in the Menu, and use the down arrow to select "**Delta T**".
2. Use the right arrow to choose the requested step.
3. Press EXIT to return to the Main Screen.

Target Temperature Setting

The Target Temperature Setting option enables selecting the rewarming Target temperature and is available only in Controlled Rewarming mode.

The Target temperature can be set between 32.0ºC (89.6ºF) to 38.0ºC (100.4ºF) with a default of 36.5ºC (97.7ºF).

NOTE: *This panel is accessible only in Controlled Rewarming mode.*

➤ ***To change the Target temperature***

1. Use the up/down arrows to modify the Target Temperature.

Figure 4-6: Target Temperature Setting Panel

Step by Step Operation

Preparing the System for Operation

WARNING!!! *Water may drip from the inlet tubes of the garments. Be sure that no electrical device or outlet is located under the CritiCoolwater inlet or garment tubes. When disconnecting garments from the CritiCool confirm that the clamps are tjght to prevent water leak from the garment.*

➤ ***To prepare the system for operation:***

1. Place the unit in the desired position according to “Space and Environmental Requirements” on page 3-1.
2. Press the brake pedals and lock the wheels to secure the CritiCool device.
3. Remove the water tank feeder cover and pour in ***cold tap water*** until the maximum allowable level is reached - **(minimum water temperature 13**ºC **/ 55.4**ºF**)**
4. Observe the water-level indicator to prevent overfilling the water tank. Close the water tank feeder cover.

NOTE: *In case of overfilling, see Table 7-1*.

5. Connect the CritiCool device to the power source.

WARNING!!! *The patient must be under constant supervision. Mishandling of temperature regulation equipment can potentially injure a patient.*

CAUTION! *Beware that complications may occur if the patient has ischemic limbs or arterial cross clamping.*

WARNING!!! *Transdermal medications (patches) can increase drug delivery, resulting in possible harm to the patient.*

Turning on the System

➤ ***To turn on the system:***

NOTE: *Make sure that tubes and sensors are disconnected.*

1. Turn the main switch, on the CritiCool system, located at the rear of the unit, upwards to the ON position
2. Following a short Self Test, the system automatically starts to cool the water.

IMPORTANT! *It is highly recommended to let the CritiCool run for 20 – 30 minutes before connecting sensors and hoses.*

3. Take the Wrap out of the package and place appropriate Wrap on bed or underneath patient (see Instructions of Use of the Wrap).

Inserting and Attaching Human Sensors

CAUTION! *For proper use of the CritiCool device, the core sensor must be inserted and the surface sensor must be attached.*

4. Insert the Core Sensor into the Patient. Insert the reusable core sensor or the disposable core sensor or connect the disposable core sensor to its adapter as soon as possible into the patient prior to fastening the Wrap.
5. Attach the reusable surface sensor or the disposable surface sensor to an exposed area of skin with adhesive tape. Immediately connect the disposable surface sensor to its adapter.

NOTE: *When using disposable sensors and adapters, make sure to connect the appropriate sensor to its adapter (note the labeling on the adapter).*

Wrapping the Patient

CAUTION! *Before securing the Wrap with the Velcro strips, fill the wrap with water .*

6. Connect Water tubes to Wrap and to the CritiCool unit. – The Wrap automatically fills up!
7. Check that clamps on Wrap are open and a clicking sound is heard.

Refer to the Instructions for Use leaflet supplied with each Wrap.

NOTE: *The Wrap does not fill with water unless the Core temperature sensor is in place.*

CAUTION! *If treatment exceeds the allowed lifetime as indicated in the leaflet, replace the Wrap.*

CAUTION! *Select the corresponding connecting tubes according to the Wrap in use.*

CAUTION! *The CritiCool device does not initiate thermoregulation if the core sensor is not properly inserted into the patient. Ensure that direct patient feedback is monitored at all times.*

Cooling Mode

When the CritiCool device starts you are prompted to confirm the mode, and an audio alarm sounds. COOLING is highlighted by default.

When Cooling mode is selected, a default Set Point (SP) temp appears on the Main Screen. The default temperature is 33.5ºC (92.3ºF) for Neonate Mode and between 33.0.ºC to 36 ºC in Adult Mode (according to the SP configured in the Settings Screen. See “Set-Point Set Up ” on page 4-9).

On the Main Screen you can change the cooling Set Point temperature for the current patient using the UP/DOWN arrows.

NOTE: *When there is a difference between the Set Point temperature and the Core temperature, a further decrease in the Set Point temperature does not affect the water temperature in the Wrap. The CritiCool device automatically operates at the optimal level to obtain the desired set-point temperature. The SP temp should therefore be set at the beginning of the cooling therapy and not changed until the patient has to be rewarmed or the desired patient temp is different than at the beginning of the treatment*

NOTE: *The cooling rate depends on the size and weight of the patient. A cooling rate of 1.5ºC / hour is the reference for the expected patient temperature change during the cooling phase.*

WARNING!!! *The default setting is intended to maintain mild hypothermia.*

WARNING!!! *The desired set point temperature should only be set by the physician or under the order of a physician.*

NOTE: *The system provides the physician with the option of selecting a body temperature in the range of $30^{O}C$ to $40^{O}C$ ($86^{O}F$-$104^{O}F$).*

After setting the set point temperature, follow the on-screen instructions and operate as instructed.

NOTE: *Short transient changes in Core temperature do not affect thermoregulation, and are compensated by the system.*

Alarm Message "Fix Sensor if out of place. Click Operate when sensor is OK"

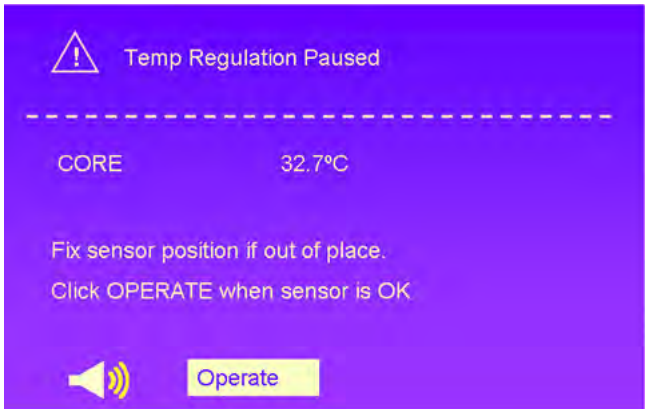


Figure 4-7: Alarm Message "Fix Sensor if out of Place.

This message indicates that the Core reading is probably in error, and Thermoregulation has stopped !!

In Adult Mode: Water continues to flow to the machine as long as the Patient temperature is above 31º*C*.

In Neonate Mode: Water immediately stops flowing to the Wrap.

Check if the Core Sensor is correctly inserted and the reading is correct:

- If the sensor needs repositioning, reposition and recheck temperature, then select OPERATE to restart temperature management (see Figure 4-7).
- If the temperature is correct you need to confirm and select OPERATION to restart temperature management.

CAUTION! *Check that the Core Sensor is properly set into the patient and choose 'OPERATE' to confirm the Core temperature.*

NOTE:*If you disregard the message and do not Press "OK" for over 30 minutes- The alarm cannot be silenced until the OPERATE button is pressed.*

When "OPERATE" is pressed, the screen returns to the Main Screen and a message appears for 5 seconds to indicate that thermoregulation has resumed.

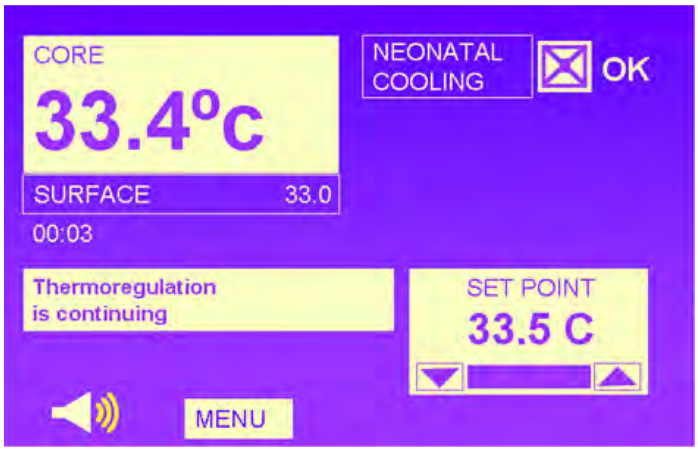


Figure 4-8: Thermoregulation is Continuing Message

Normothermia Management

Use the Normothermia Management mode for warming a patient in order to achieve or maintain Normothermia.

The CritiCool device is automatically pre-set for Cooling therapy. The device can be set to operate in Normothermia Management mode (see“Selecting Modes” on page 4-10).

Normothermia

To achieve Normothermia , set the temperature Set Point to the desired temperature.

The CritiCool device automatically operates at the optimal level to obtain the desired set-point temperature so that, when in Normothermia mode, the difference between the set point temperature and the core temperature does not affect the heating rate. A further increase in the set point temperature will not affect the water temperature in the Wrap.

Exceeding the Normothermia Range

If the desired set point temperature is set to be out of Normothermia range (32ºC or 38ºC / 96.8ºF or 100.4ºF), the message "**OUT OF NORMOTHERMIA PRESS OK TO CONFIRM**" appears. If OK, it is possible to set the set point above 38ºC or below 32ºC.

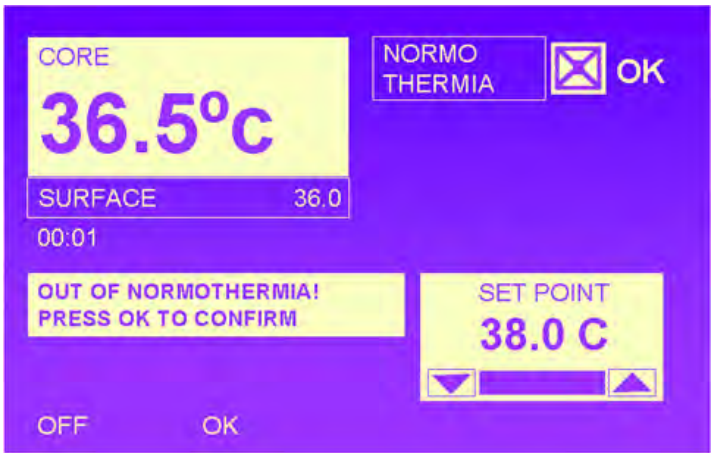


Figure 4-9: Out of Normothermia Message

Manual Rewarming

To manually rewarm the patient, select a Set Point that is slightly above the Core temperature (see “Controlled Rewarming Setup” on page 4-12) and wait until Core temperature reaches the new Set Point, increase the Set Point another step and wait for the Core temperature to reach the next step.

Repeat the procedure until the patient reaches target temperature.

The Set Point step and the duration at each step, depend on the hospital treatment policy.

When choosing small steps the CritiCool will keep water temperature close to body temperature - It is recommended to choose steps of 0.2°*C* – 0.3°*C* during the Rewarming phase.

WARNING!!! *When rewarming the patient, **always** choose a Set Point temperature that is no more than 2°C (3.6°F) above the Core temperature.*
Otherwise the CritiCool device ignores the Set Point and continues cooling !!! (If the patient is above 31°C) or goes into StandBy mode (If the Patients temp is below 31°C)!!!

For faster rewarming choose Normothermia Management mode.

WARNING!!! *The desired set point temperature should only be set by the physician or under the order of a physician.*

Controlled Rewarming Mode

This mode is used for automatic tewarming at the end of mild hypothermia treatment period.

In Controlled Rewarming mode the CritiCool increases the set-point automatically in small steps with a pre-selected duration for each step.

Controlled Rewarming Process.

The Controlled Rewarming process starts with the mild hypothermia temperature -

For example 33.5 ^{O}C, the first step of the process is to increase the *virtual* Set-Point by 0.2ºC: to 33.5 + 0.2 = 33.7ºC for a period of 30 minutes.

Assuming that at the end of the 30 minutes period, the Core temperature has reached , for example, 33.7ºC, the Rewarming algorithm adds 0.2ºC to the last virtual setpoint and the new virtual set point is now 33.7 + 0.2 = 33.9ºC for an additional 30 minutes, and so on, until the Core temperatures reaches the Target temperature. At this point the process stops and the system changes the mode to "Cooling" mode with the Set Point equal to the Target temperature.

NOTE: *To calculate the next VSP, the algorithm takes* $T_{VSP}(n)$*, and selects* $T_{VSP}(n+1) = T_{VSP}(n) + \Delta$*, irrespective of the* T_C *of the patient.*

If, however there is an additional effect, such as spontaneous increase in body temperature of $+\Delta SP$ *or spontaneous decrease in temperature of* $-\Delta SP$ *the algorithm halts the spontaneous change in temperature and force the patient to the set VSP.*

➤ ***To Start Automatic Rewarming:***

1. Use CritiCool **MENU** key to open the **MODE SELECT** panel and choose **CONTROLLED REWARMING**.

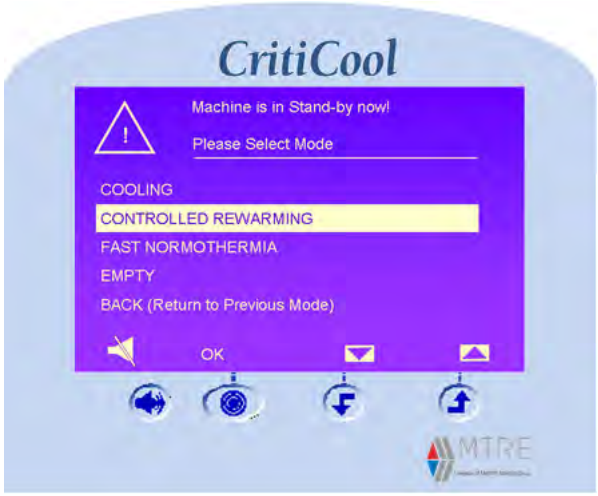


Figure 4-10: Controlled Rewarming

NOTE: *In the "Controlled Rewarming" mode, the set point display changes to "Target Temperature" with a default of 36.5 ^{O}C.*

A message appears: "**Switching to Rewarming Please confirm core in place. Click OPERATE to start Rewarming process**"

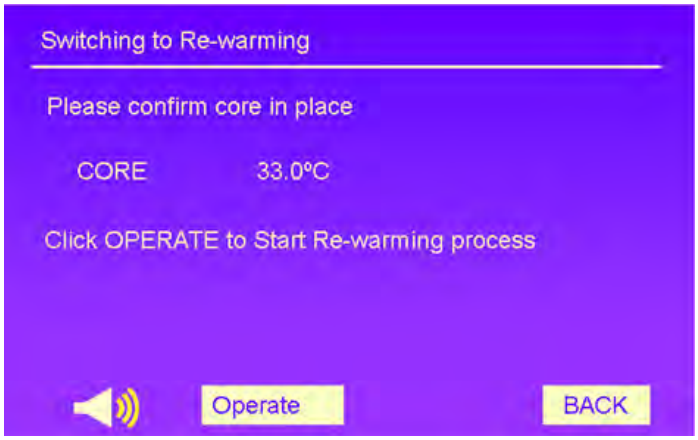


Figure 4-11: Switching to Rewarming Message

2. Press **OPERATE** to confirm Correct Core temperature and to start the Rewarming Process.
3. Use the "Target Temperature Setting" panel (see "Controlled Rewarming Mode" on page 4-19) to change the Target temperature.

NOTE: *The "Target" temperature is the temperature at which the Controlled Rewarming process ends.*

Figure 4-12: Controlled Rewarming

CritiCool heats the water, and starts circulation - The Flow icon starts to rotate.

The system proceeds to increase the *virtual* set point until the Target temperature is reached. When Core temperature reaches the Target temperature, the mode automatically changes to "COOLING" with the set point equal to the Target Temperature and the CritiCool stabilizes the body temperature accordingly.

If, during the Rewarming phase, the Core temperature TC becomes more than 2 degrees below the Target temperature, the following message appears:

Figure 4-13: "Temperature Regulation Paused" Message

Check that the Core is inserted correctly in the patient and then press OPERATE to continue Rewarming.

NOTE: *While this screen is displayed, the machine is not thermoregulating the patient and there is no water flowing to the wraps!*

Replacing the Wrap

➤ ***To replace the wrap:***

1. Use the menu to open the mode panel.
2. Select STAND-BY mode and wait for 5 minutes to let the water return (by gravitation) to the system.
3. Close Wrap clamps to avoid water spill.
4. Disconnect the connecting tubes from wrap.

WARNING!!! *Avoid disconnecting tubes above electrical equipment as mild dripping may occur during disconnection.*

5. Remove the used wrap and dispose according to hospital regulations.
6. Place the new Wrap (follow the Instructions for Use leaflet supplied with each wrap).
7. Fill the water tank with cold tap water to the required level (minimum water temperature 13°C / 55.4°F) .

8. Reconnect the connecting tubes to the new wrap.
9. Fill the new wrap with water.
10. The system is ready for treatment.

STAND-BY Mode

Use STAND-BY mode to stop thermoregulation for patient special treatment (X-Ray or Wraps replacement). In this mode there is no water circulation and thermoregulation. The CritiCool Device keeps monitoring patient temperatures, circulating the water internally and maintaining the water temperature at the appropriate level to be ready when returning to Cooling or Normothermia mode.

NOTE: *During STAND-BY mode there is no temperature regulation. Use this mode when replacing a wrap or if you need to disconnect the wrap temporarily from the machine (for example for transport or CT/MRI imaging).*

Figure 4-14: Stand-By mode

CritiCool After Use Care

Following the use of CritiCool on a patient it is recommended to drain the tank and to leave the tank empty until a new patient starts treatment.

➤ ***To maintain the system ready for the next use:***

1. After removing the patient wrap, sensors and tubes perform external cleaning and disinfecting of the system with a wet cloth (alcohol).
2. Add 1 AQUATABS tablet to the water tank with a minimum amount of 3 liters (full tank=6 liters).

3. Run the system in Standby Mode (water circulating internally) for 60 minutes.
4. Use the EMPTY Mode to drain the tank.

CAUTION! *Dispose of the CureWrap in accordance with national regulations governing non-toxic plastic waste discharge.*

Empty Mode

Figure 4-15: Empty Mode

➤ ***To empty the water tank:***

1. Disconnect the Wrap.
2. Connect an emptying tube to the "water out" of the CritiCool and direct the tube to a bucket for water collection.
3. Change the mode to **Empty.**
4. Wait for all the water to come out of the system.

CritiCool is now ready for storage until next procedure.

Operation Panel Messages

If the Wrap tubes are connected, temperature sensors are connected correctly, and Core temperature is measured, therapy will start without additional user action. If any of the above conditions is not fulfilled, the operation panel message area (bottom left) will display technical and/or clinical alarm messages.

Technical Messages

The following technical messages might appear:

- ADD WATER
- CHECK WATER CONNECTIONS
- CONNECT CORE SENSOR
- CONNECT SURFACE SENSOR
- TANK IS EMPTY
- ATTACH WATER CONNECTIONS
- CHECK CORE SENSOR
- CHECK SURFACE SENSOR

Follow the instruction of the technical messages, (for example add water if necessary, or connect sensors if they are not connected etc.).

Clinical Messages

Clinical messages call for the attention of the operator (doctor or nurse) on the condition of the patient, and /or call for user confirmation of the setting by pressing the **OPERATE** key

- OUT OF NORMOTHERMIA! PRESS OK TO CONFIRM
- PATIENT TEMPERATURE ABOVE 38.5^{O}C (101 ^{O} F)
- Fix sensor position if out of place. Click OPERATE when sensor is OK

Safety Messages

Safety messages call the attention of the users that the system has either overcooled or over heated the circulating water.

If such condition occurs the user should consider shutting down the system and finding the cause of the problem

- WATER TEMP. TOO LOW
- WATER TEMP. TOO HIGH

Informative Messages

Informative messages indicate the status of the machine.

These messages are for information only and do not require any user action.

- Low Core Temperature. Thermoregulation is continuing…
- ThermoRegulation is continuing
- Body Temp in accepted Range

Cooling Therapy Messages

The thermoregulation system may have one of three conditions

A. Core temperature above the Set point [Tc >= (Tsp-△)]

In this condition Temperature control will start without any user action

B. Core temperature is above 31°C but somewhat lower than the Set point

[30°C < Tc < (Tsp - △) , where △ = 0.8°C]

In this condition:

Temperature control continues and warms the patient toward the Set point

An Informative message appears and an audible alarm sounds.

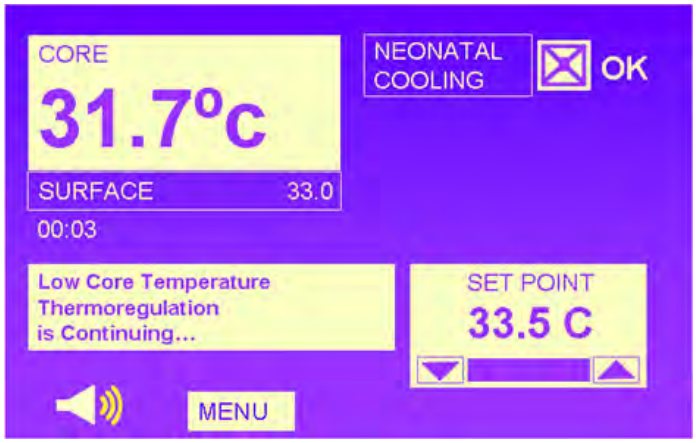


Figure 4-16: Low Core temperature

Pressing MUTE leaves the message and stops the alarm for 30 minutes.

The message is removed only where △<= 0.6°C

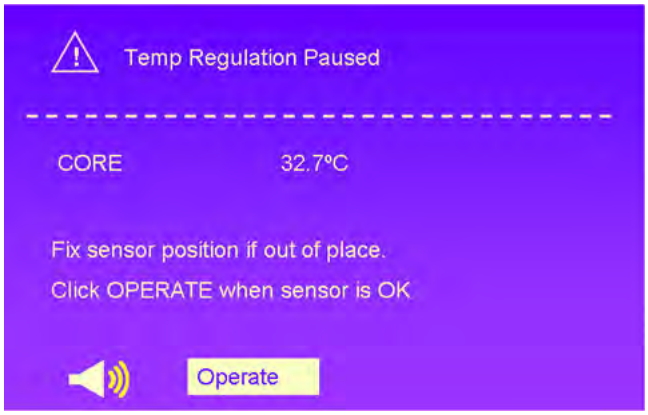
C. Core temperature is lower than the Set point by more than 2°C (△(Tsp-Tcore)> 2°C)

Or if Tc < 31°c

This means that Core sensor probably out of the body

In this condition:

The following message appears:



And an audible alarm sounds.

Pressing MUTE leaves the message. The alarm stops for 5 minutes.

When "OPERATE" is pressed, the screen returns to the Main Screen and the following message appears for 5 seconds.

NOTE:*If the Core Temperature is below 30.5°C, the alarm cannot be silenced.*

While the message appears the system status is:

a. In Adult Mode:

- **If Core> 31.0°C**: Thermoregulation is paused, but The machine continues to flow cold water to the Garment so the patient does not loose the cooling energy.
- **If Core < 31.0°C**: Thermoregulation is paused and the machine changes to Standby mode (The water stops flowing to the Garment).

b. In Neonate Mode:

Thermoregulation is paused and the machine changes to Standby mode (The water stops flowing to the Garment).

Check that the Core sensor is in place and the low temperature represents the true patient status and press "OPERATE " to re-activate temperature control.

NOTE: *If you disregard the message and do not press "OPERATE" for over 30 minutes- The alarm cannot be silenced.*

When "OPERATE" is pressed, the screen returns to the Main Screen and the following message appears for 5 seconds.

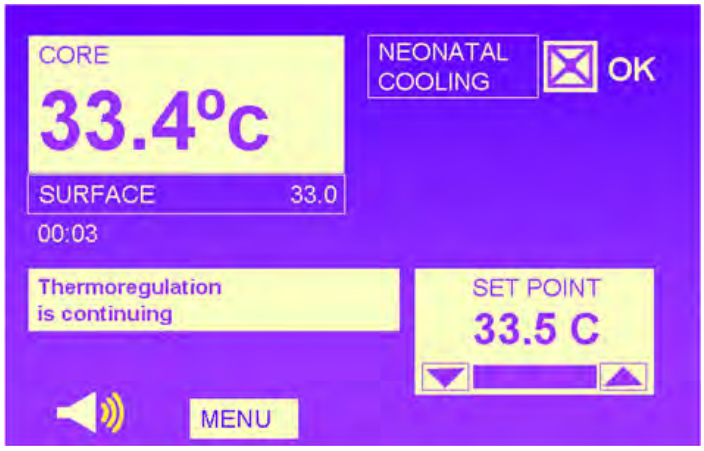


Figure 4-17: "Thermoregulation is continuing" Message

Auto Rewarming Therapy Messages

During Auto Rewarming there may be two conditions:

a. **Patient Core Temp< Target Temperature**, but **(△Virtual SP-Core Temp)< 2°C**:

In this case the machine automatically raises the patient temperature gradually to the Target temp, according to the Temp Step chosen in the Settings screen.

b. **Patient Core Temp< Target Temp** but **(△Virtual SP-Core Temp)>2°C**

This means that Core sensor is probably out of the body.

In this condition:

The following message appears:

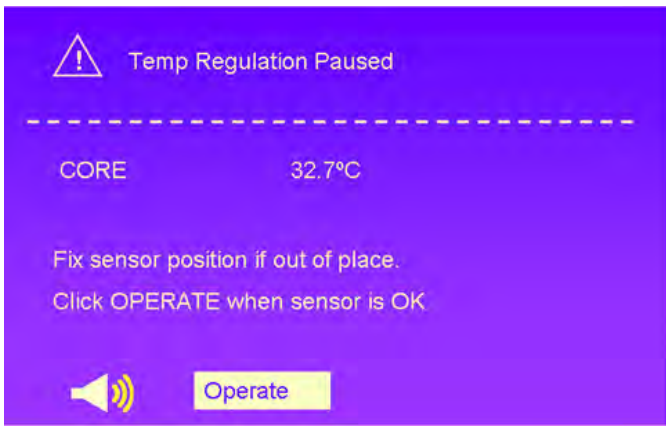


Figure 4-18: "Temp Regulation Paused " Message

And an audible alarm sounds.

Pressing MUTE leaves the message. The alarm restarts after 5 minutes.

While this message appears, The machine is not regulating the patient's temperature and no water is flowing to the garment.

Check that the core sensor is in place and the low temperature represents the true patient status and press " OK" to re-activate temperature control.

NOTE:*If the User disregards the message and does not Press "OK" for over 30 minutes- The alarm cannot be silenced.*

When "OK" is pressed, the screen returns to the Main Screen and the following message appears for 5 seconds.

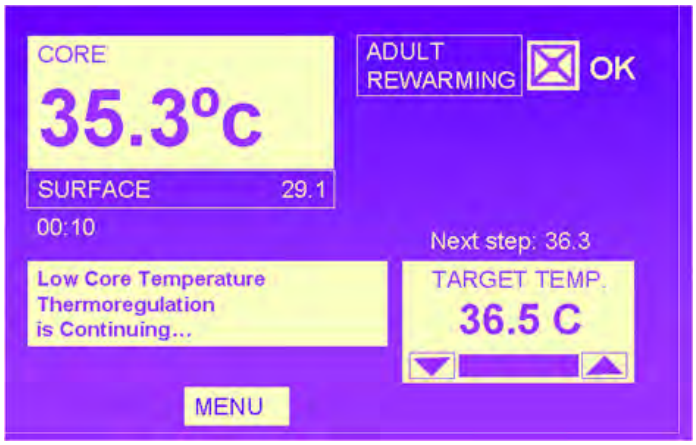


Figure 4-19: "Low Core Temperature Thermoregulation is continuing" Message

CHAPTER 5: ORDERING INFORMATION

Equipment and Accessories

All equipment and accessories may be ordered directly from your local MTRE representative. When ordering parts, specify the model number as listed in this chapter as well as the serial number of your CritiCool device.

Available Wraps

Models for various Wraps are available. Refer to Table 5-1.

Table 5-1: Wrap Information

TW/CW	*Type*	*P/N*	*Box/Single*	*Patient Size/ Weight*	*Wrap Height/ Width (m)*
Cure Wrap	**Adult**	**508-03500**	**Box (X8)**	**168-180cm (over 66")**	**2.030/1.354**
	Infant	**508-03518**	**Box (X8)**	**Up to 4Kg**	**0.659/0.448**
		508-03521	**Box (X8)**	**4-7Kg**	**0.698/0.602**
Pediatric Cure Wrap	**Small**	**PED-SM008**	**Box (x8; multi size)**	**Up to 4Kg (X4), 4-7Kg (X4)**	**0.659/ 0.4480.698/ 0.602**
	Medium	**PED-MD008**	**Box (x8; multi size)**	**7-11 Kg (X4), 79-91cm (X4)**	**0.981/ 0.6281.118/ 0.740**
	Large	**PED-LA008**	**Box (x8; multi size)**	**91-104cm (X4), 104-122 cm (X4)**	**1.225/ 0.8411.390/ 1.054**
	X-Large	**PED-XL008**	**Box (x8; multi size)**	**122-135cm (X4), Over 135cm (X4)**	**1.582/ 1.11932.030/ 1.354**

Table 5-1: Wrap Information

TW/CW	*Type*	*P/N*	*Box/Single*	*Patient Size/ Weight*	*Wrap Height/ Width (m)*
ThermoWrap	Universal	512-03131	Box (X12)	79-91cm (31"-36")	1.118/0.740
		512-03136	Box (X12)	91-104cm (36"-41")	1.225/ 0.841
		512-03141	Box (X12)	104-122 cm (41"-48")	1.390/ 1.054
		512-03148	Box (X12)	122-135cm (48"-53")	1.582/1.193
		512-03153	Box (X12)	135-152cm (53"-60")	1.744/1.212
		512-03160	Box (X12)	152-168cm (60"-66")	1.934/1.295
		512-03166	Box (X12)	168-180cm (over 66")	1.904/1.321
	Infant	524-03118	Box (X24)	2.5-4 Kg	0.659/0.448
		524-03121	Box (X24)	4-7 Kg	0.698/0.602
		524-03125	Box (X24)	7-11 Kg	0.981/0.628
	Cardiac	512-03363	Box (X12)	168-180cm (over 66")	1.348/1.319

Table 5-2: Accessory Part Numbers

Part No.	Description
200-00300	**Accessory kit - Adult Reusable**
002-00069	Connector 1/4' with hose barb
014-00020	YSI 401 Standard Adult ESo/Recta
014-00021	SURF Sensor, YSI B-C, GREEN
014-00082	Quick Reference Guide -CritCool
015-00035	Accessories Box
099-00025	Leaflet for Allon 2001 Labels
099-00065	Sensors Labels - Multilanguage C
200-00130	Filter Assy
200-00147	CureWrap Connecting Tubes

Table 5-2: Accessory Part Numbers

Part No.	Description
200-00310	**Accessory kit Adult Disposable**
002-00069	Connector 1/4' with hose barb
014-00028	Interface Cable - Core (Mal
014-00129	Interface Cable - Surface
014-00082	Quick Reference Guide -CritCool
015-00035	Accessories Box
099-00025	Leaflet for Allon 2001 Labels
099-00065	Sensors Labels - Multilanguage C
200-00130	Filter Assy
200-00147	CureWrap Connecting Tubes

200-00320	**Accessory kit Infant, Reusable**
002-00069	Connector 1/4' with hose barb
014-00005	YSI 402 Pediatric Eso/ Rectal
014-00021	SURF Sensor, YSI B-C, GREEN
014-00082	Quick Reference Guide -CritCool
015-00035	Accessories Box
099-00025	Leaflet for Allon 2001 Labels
099-00065	Sensors Labels - Multilanguage C
200-00109	ThermoWrap Connecting Tube
200-00130	Filter Assy

200-00330	**Accessory kit Infant, Disposable**
002-00069	Connector 1/4' with hose barb
014-00028	Interface Cable - Core (Mal
014-00129	Interface Cable - Surface
014-00082	Quick Reference Guide -CritCool
015-00035	Accessories Box
099-00025	Leaflet for Allon 2001 Labels
099-00065	Sensors Labels - Multilanguage C

Table 5-2: Accessory Part Numbers

Part No.	Description
200-00109	**ThermoWrap Connecting Tube**
200-00130	**Filter Assy**

CHAPTER 6: MAINTENANCE

Introduction

This chapter outlines the maintenance instructions for the CritiCool system. Qualified hospital staff may perform routine maintenance unless otherwise specified.

WARNING!!! *The repair, and servicing of the CritiCool system should be performed only by MTRE or authorized agents of MTRE.*

Service Information

When communicating with authorized MTRE representatives regarding the CritiCool system, always state the model and serial numbers on the identification label located on the rear panel of the CritiCool device (see Figure)

When communicating regarding Wraps, refer to the label on the Wrap package for lot number details.

Routine Maintenance

The CritiCool device should be periodically inspected and maintained to make sure that it remains in optimum condition.
A recommended routine inspection and maintenance schedule is provided in Table 6-1

System Calibration is performed monthly by the hospital Biomed engineer.

Safety Measures Before Service

Before sending the CritiCool to be serviced, the hospital staff should perform the regular after care procedures as outlined in CritiCool After Use Care on page 4-22, as well as the following:

1. Clean and disinfect the outer surfaces of the machine with alcohol.

2. Add 1 AQUATABS tablet to the water tank with a minimum amount of 3 liters and run the system in Standby Mode (water circulating internally) for 60 minutes.
3. Use the EMPTY Mode to drain the tank.
4. Comply with any additional Standard Hospital Procedures regarding cleaning and disinfecting the system after use.
5. Return Criticool to the original packaging for transport. This ensures that the CritiCool does not get damaged during transport.
6. If a Wrap has to be returned for inspection, pack the Wrap in a sealed bag/ package and mark it "**Used Wrap**".

System Calibration

System Calibration is initiated from the Settings mode.

The System Calibration process performs a complete check of the system by checking the functionality of the following components:

- Screen and buzzer
- Pump
- Wrap connection
- Pressure meter
- Heating and Cooling unit
- Temperature of water inflow and water outflow

Successful completion of the calibration process indicates that the CritiCool device is operational.

➤ ***To perform system calibration:***

1. In the Settings mode screen, select SYSTEM CALIBRATION.

NOTE: *Before performing System Calibration, verify that the water tank is at least a quarter full and not more than 2 liters and disconnect tubes and sensors.*

Figure 6-1: Selecting System Calibration

2. Press the right arrow key to enter System Calibration. System Calibration is initiated. The progress bar that appears on the screen indicates the calibration progress.

Figure 6-2: System Calibration in Progress

System calibration takes about 10 minutes.

When the process is complete, a message appears on the screen " SYSTEM CALIBRATION COMPLETED".

Figure 6-3: System Calibration Completed

3. Switch to the Operation screen.
4. Turn the CritiCool OFF.

Alarm System Check

The following messages and alarms should be checked and confirmed:

Messages

- Connect Core Sensor
- Check Core Sensor
- Connect Surface Sensor
- Check Surface Sensor
- Check Water Connection

Alarms

- Low Core temperature thermoregulation is continuing…
- Fix sensor position if out of place. Click Operate when sensor is OK.
- Patient Temperature above 38.5c
- Out of NormoThermia! - PRESS OK TO CONFIRM
- Water Temp Too High
- Water Temp Too Low

Sterilization of Reusable Sensors and Disposable Sensor Adapters

Use the Ethylene Oxide Method (E.T.O.) to sterilize reusable sensors and disposable sensor adapters as required by hospital/clinic protocol.

CAUTION! *Do not use the steam autoclave method to sterilize reusable sensors and disposable sensor adapters.*

Cleaning and Disinfecting Procedures for Reusable Sensors

Cleaning

Probes should be cleaned with a mild detergent and water to remove excess bio-burden and improve the effectiveness of disinfecting and sterilization.

Disinfecting

- For low-level cleaning use Cidex / glutaraldehyde
- For high-level cleaning use Cidex / glutaraldehyde dilute bleach, 70% isopropyl alcohol

Filter Replacement

NOTE:*An additional filter is supplied in the accessory box.*

The filter must be replaced every twelve months.

➤ ***To replacement the filter (by the hospital personnel):***

1. Drain the water tank (see Table 7-1, on page 7-2).
2. Remove the rear cover:
3. Unscrew the thumb captive screws at the bottom of the cover.
4. Pull the bottom part of the cover towards you and then down to release the lip from the chassis.
5. Release both the water-in and water-out tubes from the filter assembly by pressing the release ring of each end of the filter and pulling the tubes from the filter.
6. Dispose of the old filter.

➤ ***To replace the filter assembly:***

CAUTION! *The filter is marked with an arrow indicating the direction of water flow.*
You must assemble the filter in the manner indicated.

1. Connect the tubes to the new filter assembly. Insert both tubes with suitable force to ensure that they are secure.

Figure 6-4: Filter Orientation

2. Position the filter clamp in the chassis and tighten the filter clamp screw by hand.
3. Close the rear cover and tighten the thumb captive screws by hand.

Table 6-1: Inspection and Maintenance Schedule

Frequency	Inspection/Service	Performed By
Before each treatment	• Clean connecting tubes and Quick Coupling Connector with a wet cloth. • Perform a visual inspection for any mechanical failure in sensors, connecting tubes, and power cable. • Perform a visual inspection of the exterior of the CritiCool Device.	Staff
As required by hospital/clinic protocol	Routine external cleaning and disinfecting.	Staff
Monthly	System Calibration Check	BMD
Annually	Thermal verification Replace filter *	MTRE's authorized technician

* Filter replacement could be performed by BMD if needed more frequent than once a year (according to tap water quality).

NOTE:*The Wrap contains chlorine tablets (Cl) that prevent contamination of the hydraulic system of the CritiCool system.*

CHAPTER 7: TROUBLESHOOTING

General

The CritiCool device is equipped with self-testing routines that continuously monitor system operation. If a system fault or malfunction is detected, a fault message appears on the message display. Should a malfunction occur, consult the Troubleshooting Guide in The repair and servicing of the CritiCool system should be performed only by MTRE or authorized agents of MTRE.Table 7-1 and Table 7-3.

Trouble-shooting Guide

Table 7-1 lists some possible symptoms that indicate malfunctions that do not appear on the message display, their cause, and recommended actions.

Table 7-3 provides a list of fault messages that appear on the CritiCool device screen.

WARNING!!! *The repair and servicing of the CritiCool system should be performed only by MTRE or authorized agents of MTRE.*

Table 7-1: CritiCool System Malfunction (No Message) Troubleshooting Guide

Observation	Possible Problem	Action to be Taken
The power switch of the CritiCool device is set to "ON" but it is not activated and the control panel is blank.	CritiCool device is unplugged.	Check the 100, 115/230 VAC power cable connections.
	No line voltage	Call BMD
Wrap begins to leak.	The Wrap was accidentally punctured during the course of the operation.	Turn off the CritiCool device and allow the water to return to the reservoir. Replace the Wrap if possible
Water leaks from the connector between Wrap and the connecting tube.	Connecting tubes are not connected properly.	Close clamps on Wrap. Disconnect connecting tubes and re-connect connecting tubes until the click sound is heard.
	Damage to connecting tubes.	Replace connecting tubes.
	Damage to Quick Coupling Connector.	Call BMD.
Water leaks between connecting tubes and the CritiCool device.	Connecting tubes are not connected properly.	Disconnect connecting tubes from the machine and re-connect again.
	Damage to connecting tubes.	Replace connecting tubes.
	Damage to Quick coupling connector.	Call BMD.

Table 7-2: Water tank overfilling

Observation	Action to be taken
Water tank overfilled.	If it is necessary to drain the water tank because of overfilling, proceed as follows: 1 Connect one end of the ThermoWrap connecting tube to the right Quick Coupling Connector (under the Core Sensor socket). or, Connect the gray-coded end of the CureWrap connecting tube to the right Quick Coupling Connector (under the Core Sensor socket). 2 Connect the special male connector to the connecting tube: For ThermoWrap, see Figure 7-1. or, For CureWrap, see Figure 7-2. 3 Turn the CritiCool device ON. 4 Change into Operation mode. 5 Allow the excess water to drain into a receptacle, pail or sink. 6 When the desired water level has been reached, turn the CritiCool device OFF.

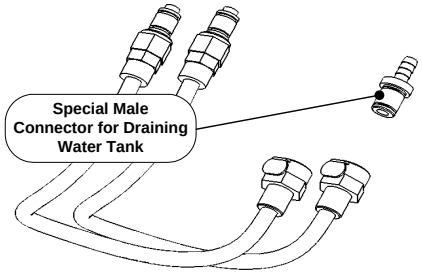


Figure 7-1: ThermoWrap Connecting Tubes and Special Male Connector

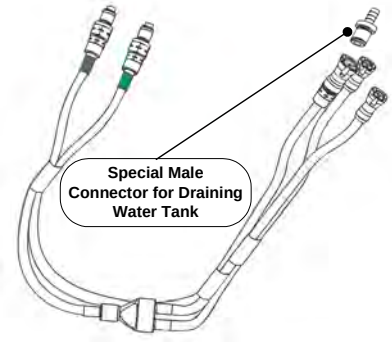


Figure 7-2: CureWrap Connecting Tubes and Special Male Connector

NOTE: *A muted alarm is activated when a subsequent message appears.*

WARNING!!! *The **HALT – PLEASE RESTART** message indicates an error that can have numerous causes. You must restart the CritiCool device.*

Table 7-3: CritiCool System Messages Troubleshooting Guide

Message	Probable Cause	Action to be Taken
- Indicates alarm activated * The alarm is activated again automatically if no action is taken.		
HALT - PLEASE RESTART	Error during normal function	Turn OFF the system for 3 seconds and then turn it ON again. If the problem persists, turn OFF the CritiCool device and contact your local service representative. Note the number that appears on the screen (1–16).
NO WATER – PLEASE ADD WATER	No water in tank	Refill water to maximum level.
	Water tank float is jammed	Open water tank cap and insert a long object to release the float.
OUT OF NORMOTHERMIA PRESS OK TO CONFIRM	**For Cooling Therapy:** Desired set-point is set to exceed 38^{o}C **For Normothermia Mode:** Desired set-point is set to be out of the Range 32°C-38°C	Approve the action if desired.

Table 7-3: CritiCool System Messages Troubleshooting Guide

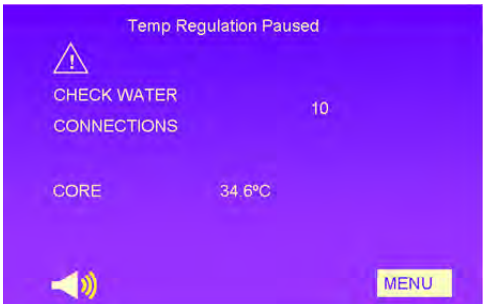
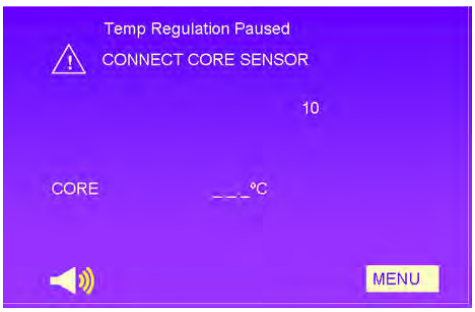
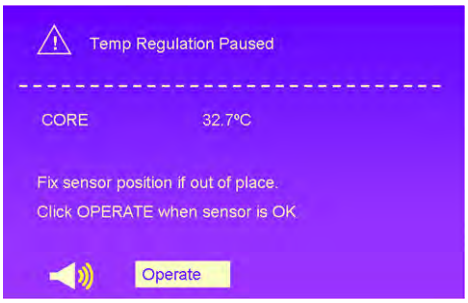
MESSAGE SCREEN:  	Connecting tubes are not connected.	Connect connecting tubes.
	Wrap is blocked due to improper wrapping	Check for snarls, folds, or objects that obstruct the water flow in the Wrap.
	Wrap clamps are closed	Check clamps **** Pressing Alarm Mute silences the buzzer for 10 minutes***
CHECK CORE SENSOR	Misplacement of sensor in core socket	Connect the core sensor to the appropriate socket.
	Core adapter is connected to the CritiCool device without the disposable temperature sensor.	Connect disposable sensor
CHECK SURFACE SENSOR	Misplacement of sensor in surface socket	Connect the appropriate surface sensor to its socket.
	Surface adapter is connected to the CritiCool device without the disposable temperature sensor.	Connect disposable sensor
MESSAGE SCREEN:  	No core sensor inserted in its socket.	Connect core sensor.

Table 7-3: CritiCool System Messages Troubleshooting Guide

WATER TEMP TOO LOW	Water Temperature < 10°C	Turn OFF the system for 3 seconds and then turn it ON again. If the problem persists, turn OFF the CritiCool device and contact your local service representative.
WATER TEMP TOO HIGH	Water Temperature > 42°	Turn OFF the system for 3 seconds and then turn it ON again. If the problem persists, turn OFF the CritiCool device and contact your local service representative.
LOW CORE TEMP. THERMOREGULATION IS CONT...	Can appear in these instances: **a. In Cooling Therapy**: Core temperature is more than 0.8ºC below set point b. I**n Normothermia Mode:** Core temperature is less than 27.0?C (80.6?F) c. **After the message** "Fix sensor Position if out of place. Click OPERATE when sensor is OK" and the OK was pressed.	No action is required. If Rewarming manually: Do not attempt to increase more than 0.8°C above actual core temperature. Pressing the MUTE button silences the alarm for 30 minutes.
PATIENT TEMP ABOVE 38.5°C (101.3ºF)	Core temperature reading above 38.5°C (101.3°F).	Inform the physician.
PATIENT TEMP BELOW 35.5ºC (95.9ºF)	27.0ºC (80.6ºF) < Temp. < 35.5ºC (95.9ºF)	Inform the physician.
ATTENTION CONNECT SURFACE SENSOR	No surface sensor inserted into the socket.	Connect surface sensor to its socket

Table 7-3: CritiCool System Messages Troubleshooting Guide

MESSAGE SCREEN:  	**In Cooling:** Core temperature is more than 2°C below set-point.	See: “Alarm Message "Fix Sensor if out of place. Click Operate when sensor is OK"” on page 4-16. Mute will silence the alarm for 5 minutes
	In Rewarming: Core Temperature is more than 2°c under the Virtual Set Point temp.	See Rewarming Therapy Message “Alarm Message "Fix Sensor if out of place. Click Operate when sensor is OK"” on page 4-16
BODY TEMP IN ACCEPTED RANGE	Core Temperature has returned to within the normal boundaries	No action is required. The message screen disappears after 5 seconds

CHAPTER 8: CLINILOGGER INSTALLATION AND OPERATING INSTRUCTIONS

Overview and Installation

Introduction

The purpose of the CliniLogger device is to save the CritiCool™/Allon2001 systems' vital data for further reference. By means of the CliniLogger Viewer software, the user can use an external PC to review this saved data.

Using the CliniLogger Application

The CliniLogger device connects to the RS-232 (serial) connector in the rear of the CritiCool™ for data transfer. While the device is connected **data is saved every one minute**

Connect the CliniLogger device to the CritiCool™ before the start of the medical procedure.

MTRE recommends recording CritiCool™ device data for one patient at a time. At the end of the procedure, disconnect the CliniLogger device from the Thermoregulation machine and connect to a PC. Download the data from the device and then reconnect the Clinlogger to the Thermoregulation machine so it is ready for the next procedure.

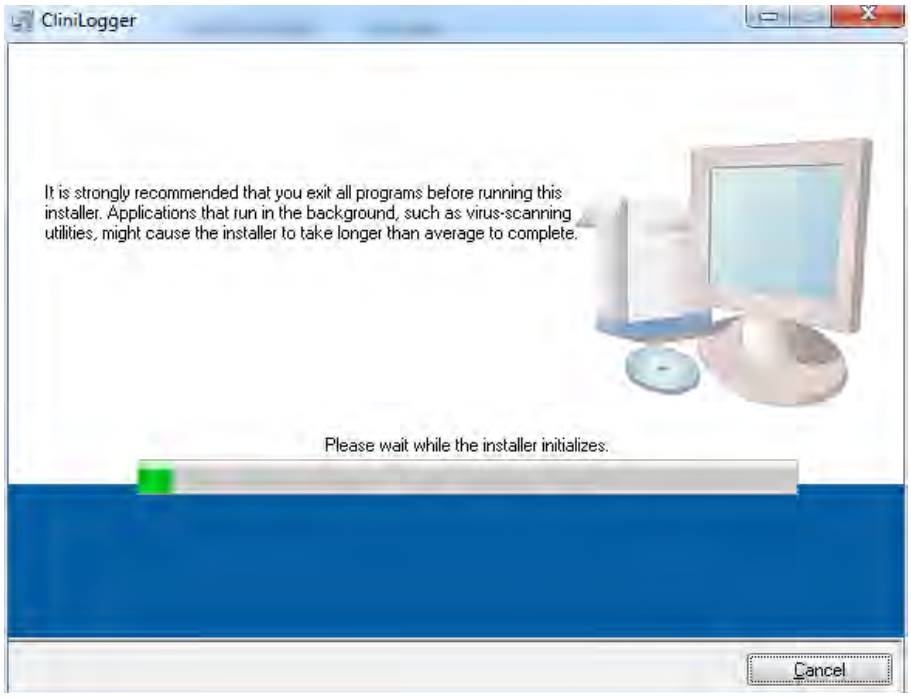
The CliniLogger Software

The CliniLogger device is supplied with a CliniLogger Viewer software CD to be installed on a PC for downloading and viewing the saved data from the CritiCool™

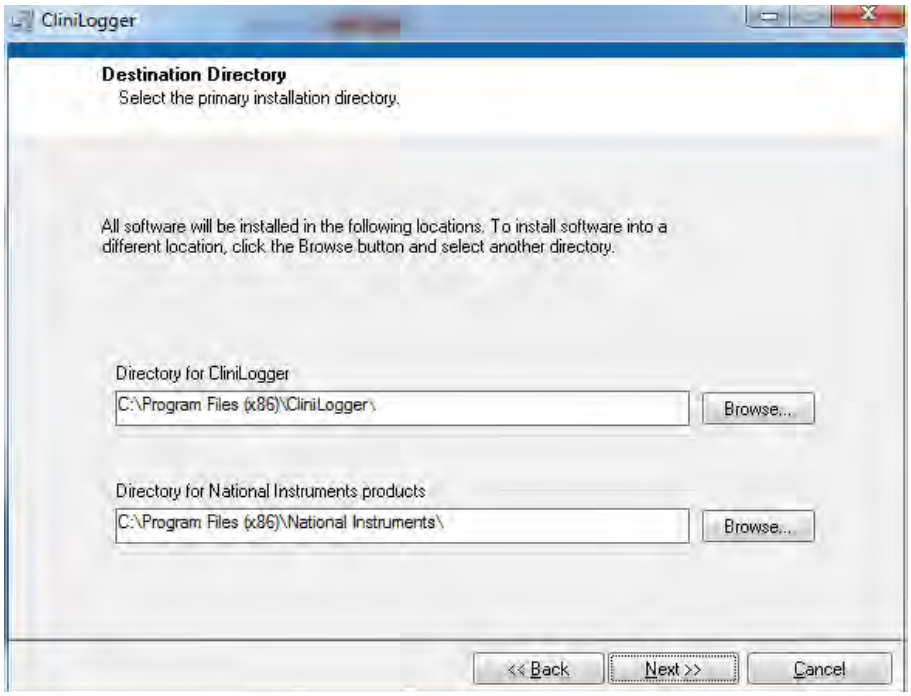
Installing the Software

➤***To install the CliniLogger software:***

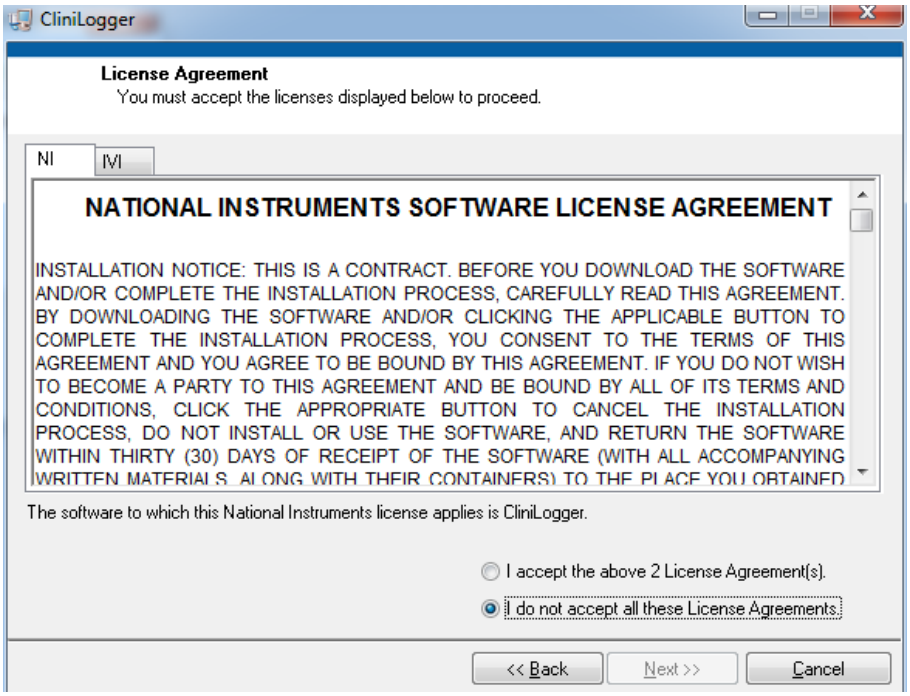
1. On your PC, double-click on **My Computer** and open the CD drive.
2. Double-click the **Installer** folder.
3. Double-click the **Volume** folder
4. Double-click **setup**; the CliniLogger install window appears.



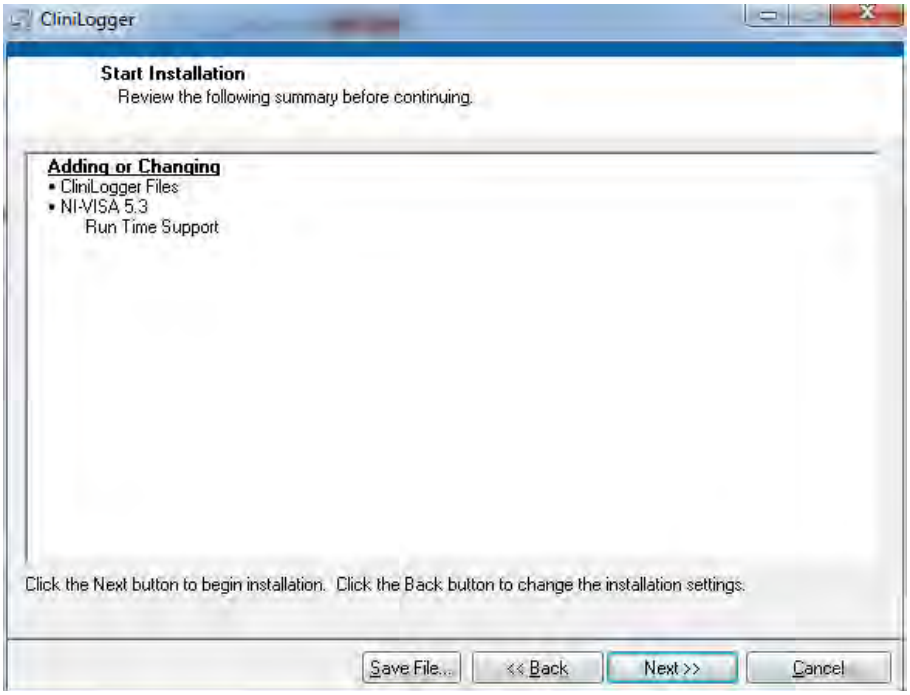
5. When initialization finishes the following screen appears.



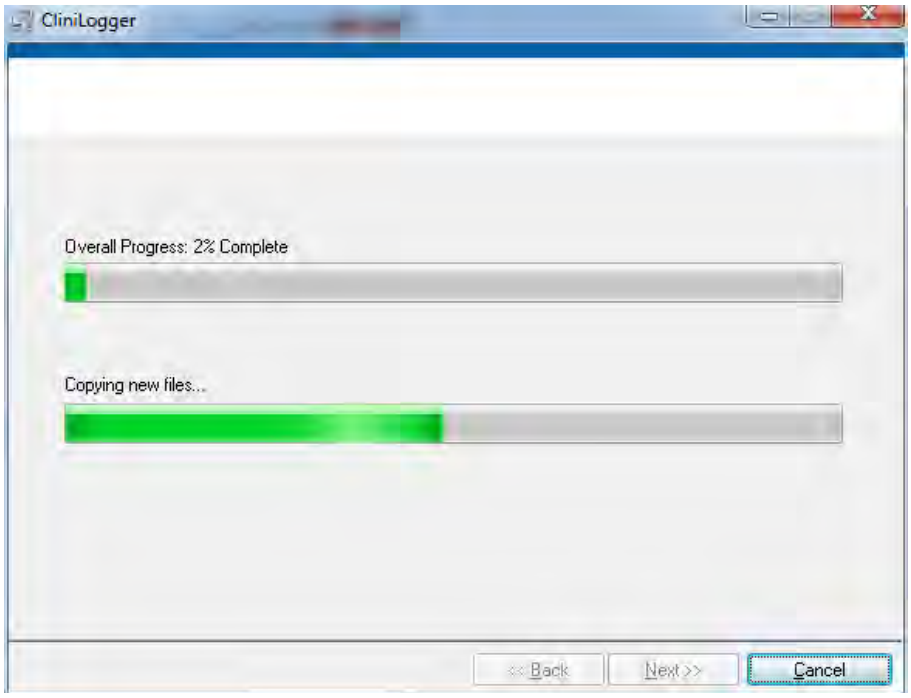
6. You can change the installation location by clicking **Browse** and selecting a new location. Click **Next.**



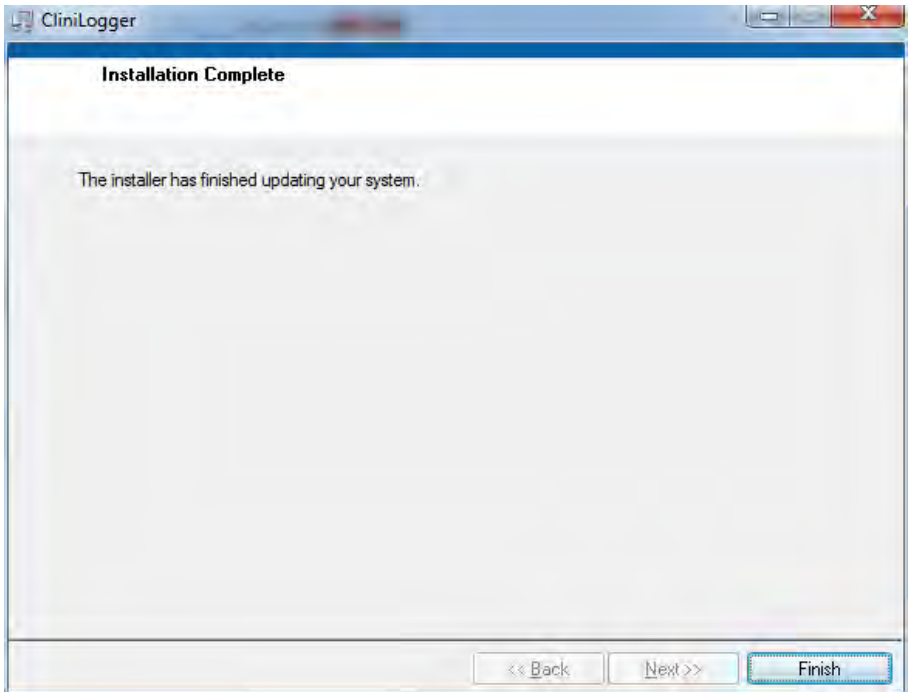
7. Select **I accept the above 2 License Agreement(s)** to accept the license agreements and click **Next**.



8. In the **Start Installation** window, click **Next**; you can follow the installation progress in the progress bars until it finishes.



9. When the installation is finished, the Installation Complete window appears; click **Finish** to complete and exit the software installation..



10. Copy "User Ver 1.3" folder from CD to your desktop, .
11. You can now open "User Ver 1.3" folder and click the Clinilogger.exe file to start the application.

Using the CliniLogger Viewer Application

Downloading Data

You can download data from the Clinilogger Device to the CliniLogger Viewer Application on the PC

➤***To start the CliniLogger application:***

1. From the Windows ***Start*** menu, click **Programs** < **CliniLogger**.
2. Click on the **CliniLogger** icon; the CliniLogger window appears.

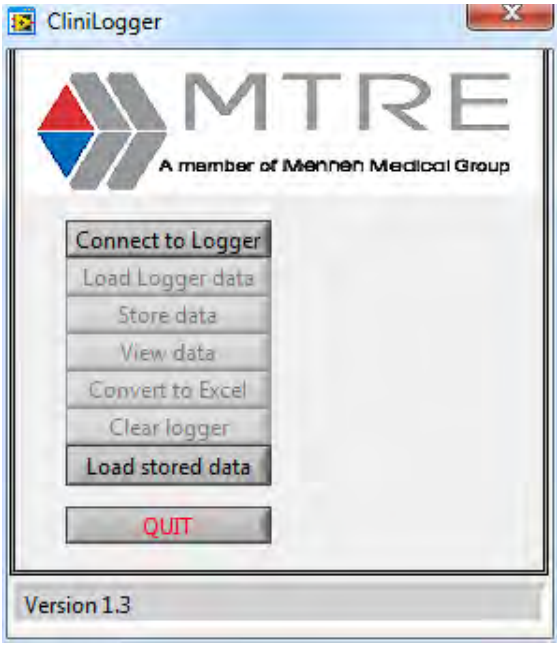


Figure 8-1: CliniLogger Application Window

3. Connect the CliniLogger device to the serial COM1 port of the PC.

NOTE:*Verify that the CliniLogger device is connected to the COM 1 –10 port or you can use with USB to RS232 adaptor.*

4. Click **Connect to Logger**, the software traces the COM port where the CliniLogger is connected – wait for the Connected message.
5. Click **Load Logger data**, wait for the Complete message.
6. Click **Store data,** and choose a file and a location.
7. Click **View data;** the graph opens.
8. You can also click **Convert to Excel** to present the data in Excel format.

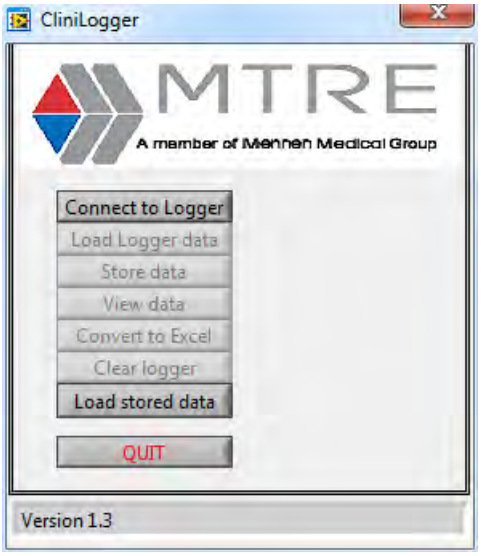
9. Click **Clear logger** after saving the data to prepare the device for the next use.

IMPORTANT! *You should erase the data on the CliniLogger manually after each patient, otherwise, the CliniLogger continues to burn data from the last patient.*

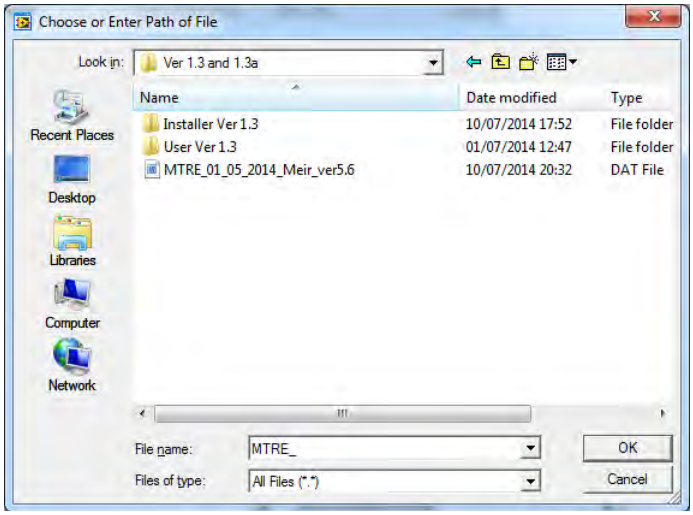
Viewing Downloaded Data

➤ ***To view downloaded data:***

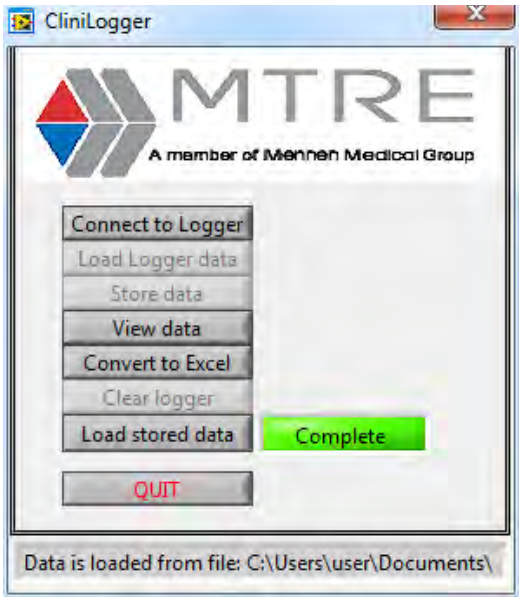
1. Double-click the CliniLogger Viewer icon. The CliniLogger window appears.



2. Click **Load stored data**, and choose the file you would like to view.



When the data has beem loaded the “Complete” message appears



3. Click **View data** - the graph opens.
4. To convert to Excel, click **Convert to Excel** – the data is presented in Excel format.

CliniLogger Viewing Panel

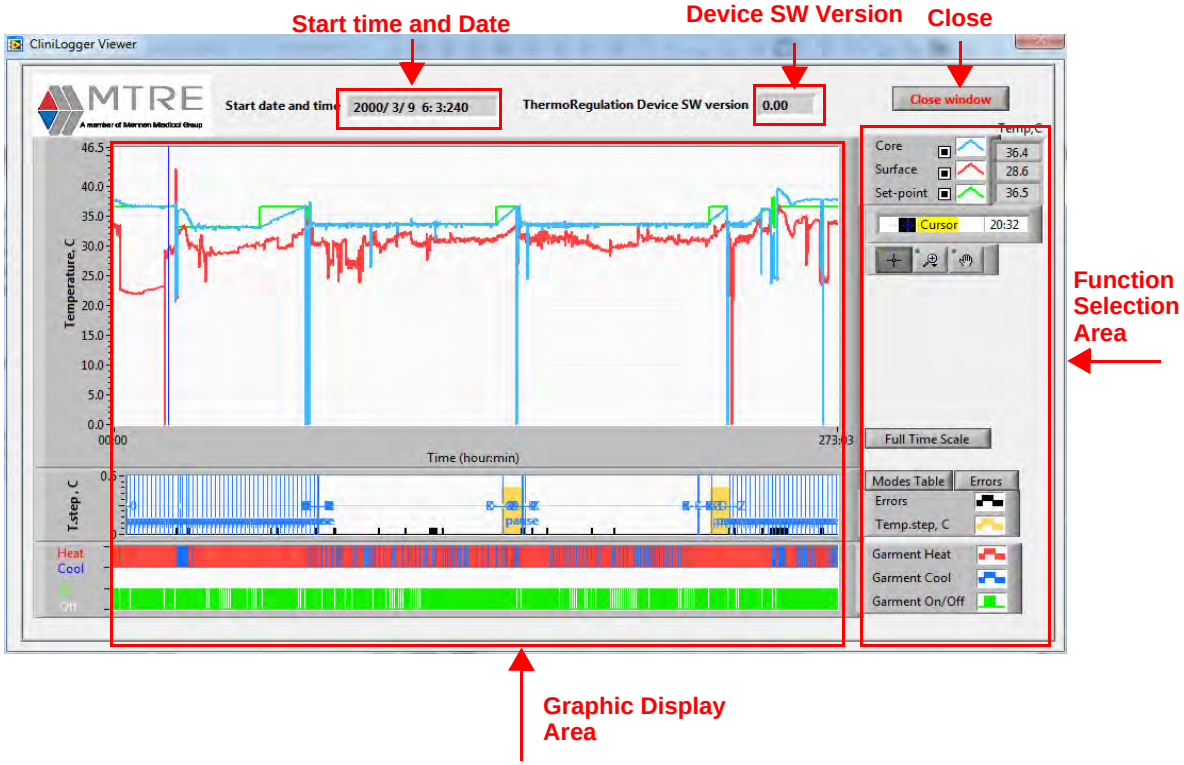


Figure 8-2: CliniLogger viewing panel

The CliniLogger viewing panel includes the following data:

- Start date and time received from the thermoregulation device (CritiCool / Allon)
- Software version of the thermoregulation device
- **Close Window** button
- Function Selection Area: Control keys
- Graphic Display Area with a graphic presentation of the Thermoregulation system variables.

Graphic Display Area

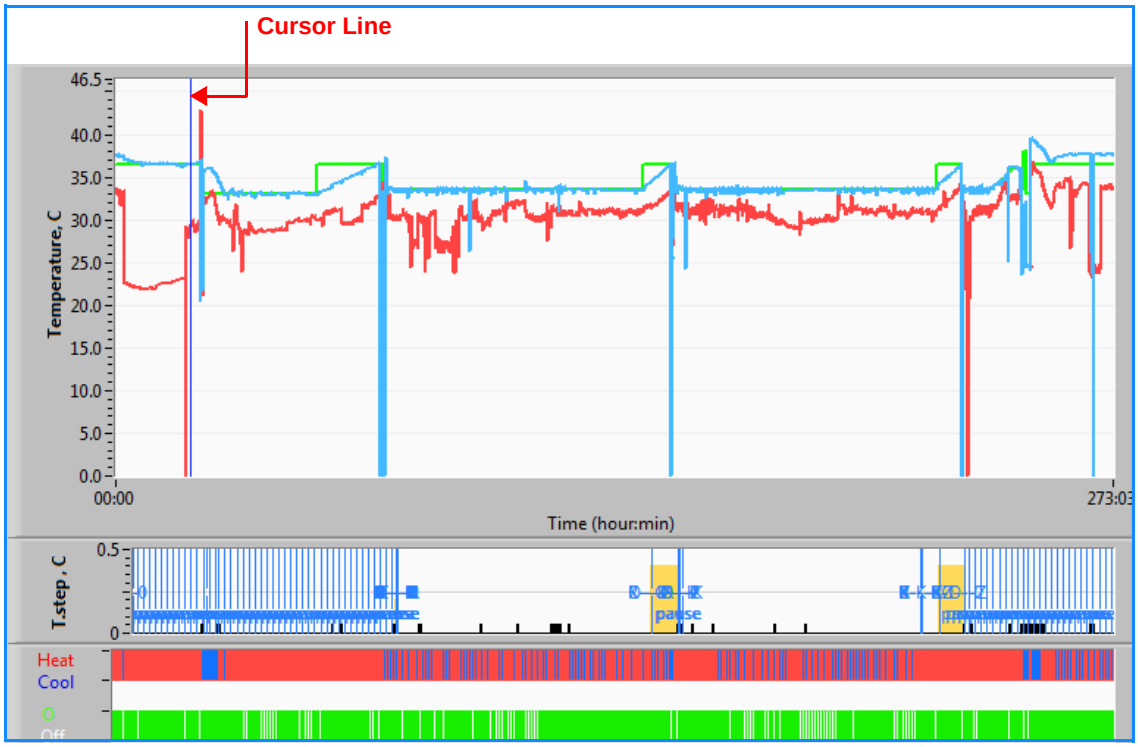


Figure 8-3: Graphic Display Area

·The Graphic Display area consists of three parts:

- **Temperatures graphs**: Set-point, Core and Surface as a function of time
- **Modes and Error area**: Thermoregulation modes, Rewarming step and errors as a function of time
- **Device Functional Status area**: Heat/Cool and Pump On/Off

Function Selection Area

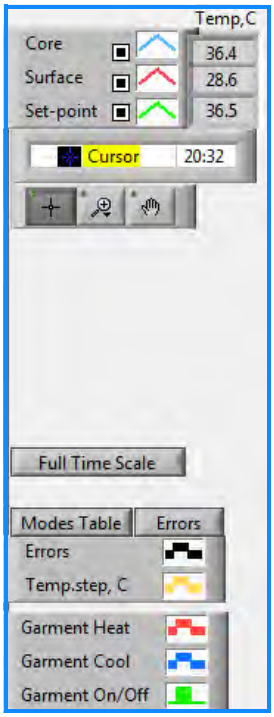
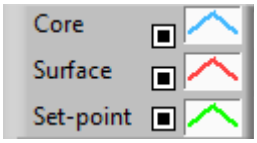


Figure 8-4: Function Selection Area

The Function Selection area includes the keys that provide the ability to modify the Graphic Display area, such as zooming in and out, moving between time zones and detailing the viewed data.

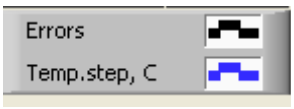
Temperature Graph Control Buttons:

These buttons define the shape of the curves in the temperature graphs area, the water heat/cool graph and the water flow graph.



Temperature Settings

Garment Settings



Errors/TempStep Settings

Temperature graph control buttons enable modifying the display of each of the temperature graphs.

Display / Hide Buttons 

Use the Temperature Setting toggle buttons to Display / Hide each of the temperature graphs.

Color Buttons 

These buttons give the abilities to change the graph features and colors.

NOTE:*It is recommended to keep the default settings.*

View Manipulation Buttons

A set of three buttons is show under the temperature buttons

Hand - Click the Hand  button, using the mouse move the hand cursor to the temperature graph area; and “grab” the curve by pressing the mouse left button and moving the mouse.

Moving the mouse horizontally will move the graphs horizontally - in time, and moving the mouse vertically, will move the graphs vertically - in temperature.

Zoom Clicking the Zoom button shows 6 modes of zoom use:

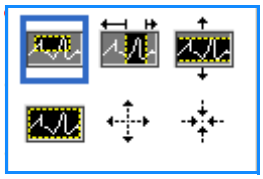


Table 8-1: Zoom Tool Buttons

Button	***Click to...***	***How to use...***
	**return the graphs to an default (un-zoomed) display**	
	**zoom out symmetrically in X and Y directions**	**Click this zoom tool button. Using the mouse move the cursor to the Temperature graph; the cursor image changes to the button icon. Click the mouse to zoom out. You can click again to zoom out again.**
	**zoom in symmetrically in X and Y directions**	**Click this zoom tool button. Using the mouse move the cursor to the Temperature graph; the cursor image changes to the button icon. Click the mouse to zoom in. You can click again to zoom in again.**

Table 8-1: Zoom Tool Buttons

Button	*Click to...*	*How to use...*
	**create an XY box zoom in box.**	**Click this zoom tool button. Using the mouse move the cursor to the Temperature graph; the cursor image changes to zoom icon. Press the left mouse button and select the box in the graph for zooming in. Once you release the mouse button the image is zoomed in.**
	**zoom in, in the X (Time) direction.**	**Click this zoom tool button, using the mouse move the Zoom tool cursor to the required point of time, click to insert the low limit line, keep the left key pressed and pull horizontally to the end of the interesting time. Once you release the mouse button the image is zoomed in.**
	**zoom in, in the Y (Temperature) direction.**	**Use the mouse move the Zoom tool cursor to the lower temperature limit, click to insert the low limit line, keep the left key pressed and pull vertically. Release the key to view the temperature graphs zoomed in the selected vertical area.**

➤***To return to full time scale after zoom actions:***

1. Click on 

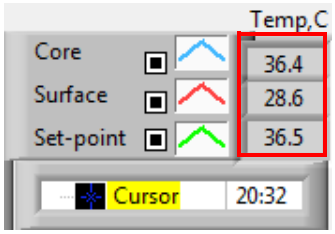
.

   The graph returns to the full time range, without affecting the Temperature scale.

NOTE: *To return to the original display click the unzoom button*  .

Cursor Line

The values of the temperatures at the cursor line location (see Figure 8-1) appear in the window adjacent to the curve color window



You can change the time of the Cursor Line on the graph (see Figure 8-3).

➤***To set the time of the cursor:***

1. Use the keyboard to set the required time in the **Cursor** textbox. Make sure to

select the time as displayed on the graph (and in the HH:MM format).

2. Press ENTER.

The cursor moves to the selected time spot and the Temperaturesdisplayed are the temperatures of the new spot.

➤***To move the cursor line, in time (X direction)***

1. Click the Cursor  icon.
2. Bring the + to the cursor location, The + will convert to a double line 
3. Use the mouse to move the double line to a new cursor location.

NOTE:*The value of the temperatures at the cursor location appears in the window adjacent to the curve color window*

Modes and Error Area

This area provides the following information:

·**Treatment mode** marked by letters (See Table 8-2) and a vertical line.

Example :

J-Cooling Adult, N-Rewarming Adult, K – Cooling etc.

·**Rewarming** step between 0º*C* and 0.5º*C* shown in the example in pink (the step was first 0.4º*C* and then changed to 0.2º*C*)

·**Error** – Period with no control , in the example due to system pause (yellow marking)

Table 8-2: Mode Codes

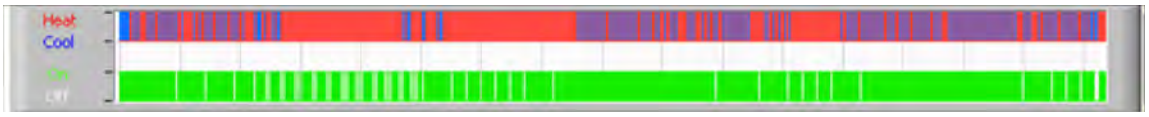
Code	Indicates		
A	PowerUp	Cooling	Adult
B	PowerUp	Cooling	Neonate
C	PowerUp	Warming	Adult
D	PowerUp	Warming	Neonate
E	PowerUp	Rewarm	Adult

Table 8-2: Mode Codes

Code	Indicates		
F	PowerUp	Rewarm	Neonate
G	PowerUp	StandBy	
H	PowerUp	Sel.Mode	Adult
I	PowerUp	Sel.Mode	Neonate
J	Cooling	Adult	
K	Cooling	Neonate	
L	Warming	Adult	
M	Warming	Neonate	
N	Rewarming	Adult	
O	Rewarming	Neonate	
P	StandBy		
Q	Select Mode		Adult
R	Select Mode		Neonate

State Area – Heat/Cool and Pump On/ Power Off

The graphs indicats the state of the garment: **Heat / Cool** modes and the **On/Off of water circulation** in the garment.



Heat/Cool- When CritiCool is cooling the water in the tank- the line is blue. When the device is warming the Water in the Tank- the line is red.

Pump On/Off- When the Pump is pumping water into the Wrap- the line is green. When CritiCool is circulating the water internally (i.e. in "Standby mode") the line is white.

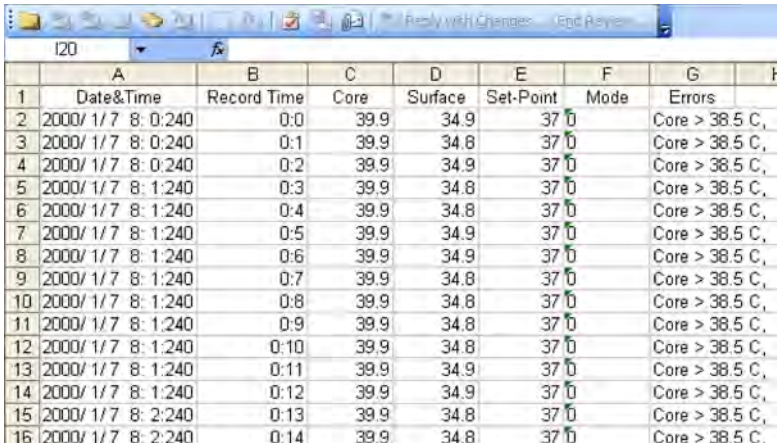
Converting to Excel

➤ ***To convert to Excel:***

1. On the CliniLogger menu panel (see Figure 8-1) select **Convert to Excel**; an Excel file opens with two options:

Measurement Table (Sheet 1)

See below Figure 4

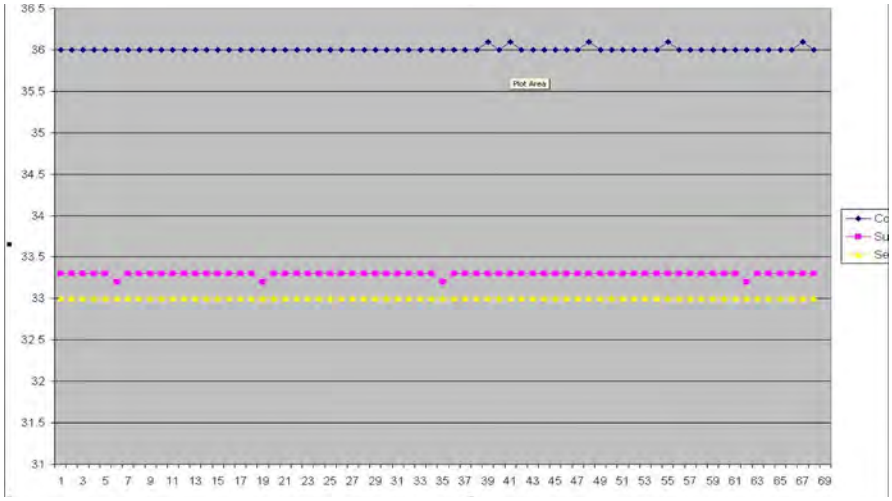


	A	B	C	D	E	F	G
1	Date&Time	Record Time	Core	Surface	Set-Point	Mode	Errors
2	2000/ 1/ 7 8: 0:240	0:0	39.9	34.9	37.0		Core > 38.5 C,
3	2000/ 1/ 7 8: 0:240	0:1	39.9	34.8	37.0		Core > 38.5 C,
4	2000/ 1/ 7 8: 0:240	0:2	39.9	34.9	37.0		Core > 38.5 C,
5	2000/ 1/ 7 8: 1:240	0:3	39.9	34.8	37.0		Core > 38.5 C,
6	2000/ 1/ 7 8: 1:240	0:4	39.9	34.8	37.0		Core > 38.5 C,
7	2000/ 1/ 7 8: 1:240	0:5	39.9	34.9	37.0		Core > 38.5 C,
8	2000/ 1/ 7 8: 1:240	0:6	39.9	34.9	37.0		Core > 38.5 C,
9	2000/ 1/ 7 8: 1:240	0:7	39.9	34.8	37.0		Core > 38.5 C,
10	2000/ 1/ 7 8: 1:240	0:8	39.9	34.8	37.0		Core > 38.5 C,
11	2000/ 1/ 7 8: 1:240	0:9	39.9	34.8	37.0		Core > 38.5 C,
12	2000/ 1/ 7 8: 1:240	0:10	39.9	34.8	37.0		Core > 38.5 C,
13	2000/ 1/ 7 8: 1:240	0:11	39.9	34.9	37.0		Core > 38.5 C,
14	2000/ 1/ 7 8: 1:240	0:12	39.9	34.9	37.0		Core > 38.5 C,
15	2000/ 1/ 7 8: 2:240	0:13	39.9	34.8	37.0		Core > 38.5 C,
16	2000/ 1/ 7 8: 2:240	0:14	39.9	34.8	37.0		Core > 38.5 C,

Figure 8-5: Section of Excel Table

Graphic Chart

A second page in the Excel file shows a graphic description of the Excel table with the Y axis showing the temperatures, and the X axis the Excel table lines



Ending a Viewing Session

➤ ***To end a session:***

Click **Quit** on the Main Menu to exit the Viewing Session.

APPENDIX A: MTRE LTD. CUSTOMER SERVICE REPRESENTATIVE

WARNING!!! *The following details are necessary to contact your MTRE representative. Keep this form with the User's Manual for easy access in case your CritiCool device is in need of service.*

Representative Name:	
Company Name:	
Address:	
Telephone No:	
Fax:	
E-mail:	

APPENDIX B: RF SEPARATION

The Criticool plus Clinilogger and Wraps Scanner device are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Criticool plus CliniLogger and Wraps Scanner device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Criticool plus CliniLogger and Wraps Scanner device as recommended below, according to the maximum output power of the communications equipment.

Recommended separation distances between portable and mobile RF communications equipment and the CritiCool plus Clinilogger and Wraps Scanner device are given in Table B-1

Table B-1: Separation Distances in meters

	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of transmitter W	**150 kHz to 80 MHz** $d = [\frac{3,5}{E1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{V1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{7}{E1}]\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed in the table, the recommended separation distance **d** in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

NOTE: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*